

NTP Historical Controls Report

By Route and Vehicle

F 344/N RATS

June 2013

REPORT DESCRIPTION

This report shows the tumor rates of control group animals from selected studies. The studies used are shown on the Study Summary page.

This report is broken up into sections based on the route and vehicle used to deliver the chemical. The Table of Contents on Page 3 shows the different Route/Vehicle combinations. To see the data from all routes and vehicles combined into one set, you must run the "All Routes" report.

The individual tumor rates shown on the data pages of the report relate to the Study Summary page as follows: the tumor rates are shown in the same order as the Study Summary page, except that they are grouped horizontally in sets of three, with the males in the first set of three and the females in the second set. For example if the study summary showed the studies like this:

Male
M1
M2
M3
M4
M5
Female
Female F1
F1
F1 F2

the data would be shown as:

	Male			Female	
M1	M2	M3	F1	F2	F3
M4	M5		F4	F5	

Directly beneath the individual tumor rates on the data pages are the overall totals for that tumor/site combination. This includes the total tumors/animals, the overall mean (in parentheses), the mean of the study means, and the standard deviation of the study means.

Studies with no control animals of a particular gender are listed on the summary page with the Number of Animals shown as zero and the Start Date and Length of Study shown as "N/A". On the data pages there are blank spaces where tumor rates for these studies would normally be found, so that the male and female rates for the remaining studies can be easily compared.

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Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

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Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory	059903103	03/23/05	727	50(3)	38(706)	512.7	Ginkgo biloba extract
Battelle Columbus Laboratory	052000705	08/18/04	727	49(3)	34(692)	515.2	Kava kava extract
Battelle Columbus Laboratory	052010703	10/20/04	727	50(3)	37(702)	503.5	N,N-Dimethyl-p-toluidine
					Female		
Battelle Columbus Laboratory	059903103	03/24/05	728	50(5)	37(700)	350.7	Ginkgo biloba extract
Battelle Columbus Laboratory	052000705	08/19/04	728	50(5)	34(683)	354.3	Kava kava extract
Battelle Columbus Laboratory	052010703	10/21/04	728	50(5)	33(704)	354.1	N,N-Dimethyl-p-toluidine

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male				Female	
All Organs: Benign Tumors								
		50/50 (100%)	49/49 (100%)	48/50 (96%)		47/50 (94%)	43/50 (86%)	46/50 (92%)
Overall Incidence	Total	147/149 (98.66%)	Mean 98.67%	SD 2.31%	Total	136/150 (90.67%)	Mean 90.67%	SD 4.16%
All Organs: Malignant Tumors								
-		13/50 (26%)	17/49 (35%)	20/50 (40%)		12/50 (24%)	11/50 (22%)	23/50 (46%)
verall Incidence	Total	50/149 (33.56%)	Mean 33.56%	SD 7.07%	Total	46/150 (30.67%)	Mean 30.67%	SD 13.32%
All Organs: Malignant and Benign Tu	mors	E0/E0 (4009/)	40/40 (400%)	40/50 (099/)		40/50 (089/)	46/50 (020/)	40/50 (000/)
verall Incidence	Total	50/50 (100%)	49/49 (100%)	49/50 (98%) SD 1.15%	Total	49/50 (98%)	46/50 (92%) Mean 96%	49/50 (98%) SD 3.46%
overali incidence	ıotai	148/149 (99.33%)	Mean 99.33%	ו עפ וווים	Total	144/150 (96%)	iviean 96%	SD 3.40%
All Organs: Hemangioma		0/50 (0%)	0/40 (00/)	4/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
verall Incidence	Total	0/50 (0%) 1/149 (0.67%)	0/49 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
						, ,		
All Organs: Hemangiosarcoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
All Organs: Hemangiosarcoma or He	mangioma							
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 6

			Male			Female				
#All Organs: Histiocytic Sarcoma										
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
All Organs: Leukemia: Lymphocytic,	Monocytic, M	Iononuclear, or Undiffere	ntiated							
		9/50 (18%)	7/49 (14%)	14/50 (28%)		8/50 (16%)	5/50 (10%)	15/50 (30%)		
Overall Incidence	Total	30/149 (20.13%)	Mean 20.1%	SD 7.09%	Total	28/150 (18.67%)	Mean 18.67%	SD 10.26%		
All Organs:		nphocytic, Mixed, NOS, o 0/50 (0%)				0/50 (0%)	1/50 (2%)	0/50 (0%)		
Overall Incidence	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%		
#All Organs: Mesothelioma: Benign, N		s	3/49 (6%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		3/50 (6%)	3/43 (070)	., 55 (=,75)		0/30 (0/0)	0/00 (0/0)	0,00 (0,70)		
Overall Incidence	Total	3/50 (6%) 7/149 (4.7%)	Mean 4.71%	SD 2.35%	Total	0/150 (0%)	Mean 0%	SD 0%		
		7/149 (4.7%)	Mean 4.71 [°] %	SD 2.35%	Total	0/150 (0%)	Mean 0%	SD 0%		
All Organs: Mesothelioma: Malignan	t	7/149 (4.7%) 3/50 (6%)	Mean 4.71% 3/49 (6%)	SD 2.35% 1/50 (2%)		0/150 (0%)	Mean 0% 00 00 00 00 00 00 00 00 00 00 00 00	SD 0% 0/50 (0%)		
All Organs: Mesothelioma: Malignan		7/149 (4.7%)	Mean 4.71 [°] %	SD 2.35%	Total Total	0/150 (0%)	Mean 0%	SD 0%		
Overall Incidence #All Organs: Mesothelioma: Malignan Overall Incidence #All Organs: Osteoma	t	7/149 (4.7%) 3/50 (6%)	Mean 4.71% 3/49 (6%)	SD 2.35% 1/50 (2%)		0/150 (0%)	Mean 0% 00 00 00 00 00 00 00 00 00 00 00 00	SD 0% 0/50 (0%)		
#All Organs: Mesothelioma: Malignan Overall Incidence #All Organs:	t	7/149 (4.7%) 3/50 (6%)	Mean 4.71% 3/49 (6%)	SD 2.35% 1/50 (2%)		0/150 (0%)	Mean 0% 00 00 00 00 00 00 00 00 00 00 00 00	SD 0% 0/50 (0%)		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male				Female	
#All Organs: Osteosarcoma								
Overall Incidence	Total	0/50 (0%) 2/149 (1.34%)	1/49 (2%) Mean 1.35%	1/50 (2%) SD 1.17%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
All Organs: Osteosarcoma or Osteoma								
Overall Incidence	Total	0/50 (0%) 2/149 (1.34%)	1/49 (2%) Mean 1.35%	1/50 (2%) SD 1.17%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Adrenal Cortex: Adenoma								
Overall Incidence	Total	0/50 (0%) 1/149 (0.67%)	0/49 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 3/150 (2%)	0/50 (0%) Mean 2%	3/50 (6%) SD 3.46%
Adrenal Cortex: Carcinoma						0/50 /00/\	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 1/149 (0.67%)	1/49 (2%) Mean 0.68%	0/50 (0%) SD 1.18%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Adrenal Medulla: Pheochromocytoma Benign								
Overall Incidence	Total	11/50 (22%) 22/149 (14.77%)	5/49 (10%) Mean 14.73%	6/50 (12%) SD 6.36%	Total	2/50 (4%) 7/150 (4.67%)	3/50 (6%) Mean 4.67%	2/50 (4%) SD 1.15%
Adrenal Medulla: Pheochromocytoma Comple	ex							
Overall Incidence	Total	0/50 (0%) 1/149 (0.67%)	0/49 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male				Female					
*Adrenal Medulla: Pheochromocytoma Malignant 2/50 (4%) 0/49 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%)												
		2/50 (4%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	3/149 (2.01%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%				
Adrenal Medulla: Pheochromocytoma: E	Benign, Comple	x, Malignant, NOS										
·		12/50 (24%)	5/49 (10%)	8/50 (16%)		2/50 (4%)	3/50 (6%)	2/50 (4%)				
Overall Incidence	Total	25/149 (16.78%)	Mean 16.73%	SD 6.93%	Total	7/150 (4.67%)	Mean 4.67%	SD 1.15%				
Blood Vessel: Leiomyosarcoma	•••••											
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%				
Bone: Chordoma												
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%				
#Bone: Osteoma												
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%				
#Bone: Osteosarcoma												
		0/50 (0%)	1/49 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	2/149 (1.34%)	Mean 1.35%	SD 1.17%	Total	0/150 (0%)	Mean 0%	SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male				Female	
#Bone: Osteosarcoma or Osteoma								
		0/50 (0%)	1/49 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/149 (1.34%)	Mean 1.35%	SD 1.17%	Total	0/150 (0%)	Mean 0%	SD 0%
Brain: Glioma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Brain: Glioma Benign				0.50				
	-	0/50 (0%)	0/49 (0%)	0/50 (0%)	-	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Brain: Glioma Malignant								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma, Glioma,								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Brain: Osteosarcoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

d Control Animal Groups Report Date: 06/05/2013
AVAGE

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			Male			Female				
Clitoral/Preputial Gland: Adenoma										
Overall Incidence	Total	4/50 (8%) 4/149 (2.68%)	0/49 (0%) Mean 2.67%	0/50 (0%) SD 4.62%	Total	5/50 (10%) 12/150 (8%)	2/50 (4%) Mean 8%	5/50 (10%) SD 3.46%		
Clitoral/Preputial Gland:										
Overall Incidence	Total	0/50 (0%) 1/149 (0.67%)	1/49 (2%) Mean 0.68%	0/50 (0%) SD 1.18%	Total	0/50 (0%) 2/150 (1.33%)	2/50 (4%) Mean 1.33%	0/50 (0%) SD 2.31%		
Clitoral/Preputial Gland: Carcinoma or Adenoma		4/50 (00/)	4/40 /00/	0/50 (09/)		E/EQ (400()	A/EO (99/)	E/EO (400()		
Overall Incidence	Total	4/50 (8%) 5/149 (3.36%)	1/49 (2%) Mean 3.35%	0/50 (0%) SD 4.16%	Total	5/50 (10%) 14/150 (9.33%)	4/50 (8%) Mean 9.33%	5/50 (10%) SD 1.15%		
Clitoral/Preputial Gland: Sarcoma					••••••					
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
#Ear: Neural Crest Tumor										
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%		
#Eye: Melanoma Benign										
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male				Female		
#Eye: Melanoma Malignant									
		0/50 (0%)	0/49 (0%)	`	0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
#Harderian Gland: Adenoma									
		0/50 (0%)	0/49 (0%)	0/50 (0	0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
Harderian Gland: Carcinoma									
		0/50 (0%)	0/49 (0%)	`	0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
Harderian Gland: Carcinoma or Adenoma		0(50 (00()	0/40 (00/)	0/50 /6	20/	0/50 (00/)	0/50 (000)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0 SD 0%	0%) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
		0/149 (0/0)							
Heart: Schwannoma Benign		0.750 (001)	2/12 (22/)	2/20		0/50 (00)	2/52 (224)	2/22 (221)	
	.	0/50 (0%)	0/49 (0%)	`	D%) —	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
Heart: Schwannoma Malignant									
		0/50 (0%)	0/49 (0%)	,	0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Intestine Large: Colon/Rectum: Adenoma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Intestine Large: Colon/Rectum: Carcinoma or Adenoma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Intestine Small: Duodenum: Leiomyoma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Intestine Small: Duodenum: **Schwannoma Malignant** 0/50 (0%)0/49 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% Total 1/150 (0.67%) Mean 0.67% SD 1.15% 0/149 (0%) #Intestine Small: Ileum: Adenoma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Intestine Small: Jejunum: Carcinoma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% 0/150 (0%) Mean 0% SD 0% 0/149 (0%) Total

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male				Female	
#Intestine Small: Jejunum Leiomyoma	:							
Overall Incidence	Total	1/50 (2%) 1/149 (0.67%)	0/49 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Jejunum Leiomyosarcoma								
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
Intestine Small: Site Uns Adenoma	pecified:							
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Intestine Small: Site Uns Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Intestine Small: Site Uns Carcinoma or Adenoma	pecified:	•••••						
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Intestine Small: Site Uns Leiomyoma	pecified:							
Overall Incidence	Total	1/50 (2%) 1/149 (0.67%)	0/49 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

PS Report Date: 06/05/2013

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			Male				Female				
#Intestine Small: Site Unspecified: Leiomyosarcoma											
Overell Institutes	Tatal	0/50 (0%)	0/49 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%			
Intestine Small: Site Uns Schwannoma Malignan	•										
		0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%			
'Islets, Pancreatic: Adenoma		4/50 (00/)	4/40 (00%)	2/50 /40/\		4/50 /00/	4/50 (20/)	0/50 /09/			
Overall Incidence	Total	4/50 (8%) 10/149 (6.71%)	4/49 (8%) Mean 6.72%	2/50 (4%) SD 2.36%	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%			
		10/149 (0.7170)									
Islets, Pancreatic: Carcinoma											
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%			
Islets, Pancreatic: Carcinoma or Adenoma	a										
		4/50 (8%)	4/49 (8%)	3/50 (6%)		1/50 (2%)	1/50 (2%)	0/50 (0%)			
Overall Incidence	Total	11/149 (7.38%)	Mean 7.39%	SD 1.2%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%			
*Kidney: Pelvis and Trans Papilloma	sitional Epitheli	um:									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 15

			Male		Female				
*Kidney: Renal Tubule: Adenoma									
Overall Incidence	Total	0/50 (0%) 1/149 (0.67%)	0/49 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
		1/149 (0.07 /6)			10tai				
Kidney: Renal Tubule: Carcinoma									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
'Kidney: Renal Tubule: Carcinoma or Adenoma		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 1/149 (0.67%)	0/49 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/30 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
•••••		, ,							
Kidney: Renal Tubule: Lipoma		4/50 (00()	0/40 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	1/50 (2%) 1/149 (0.67%)	0/49 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
		1/149 (0.07/6)			10tai				
Kidney: Renal Tubule: Mesenchymal Tumor Malig	gnant								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
Kidney: Renal Tubule: Sarcoma									
• "	.	0/50 (0%)	0/49 (0%)	0/50 (0%)	.	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 16

			Male			Female					
*Liver: Hepatocellular Adenoma											
		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%	Total	0/150 (0%)	Mean 0%	SD 0%			
Liver: Hepatocellular Carcinoma											
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%			
Liver: Hepatocellular Carcinoma	or Hepatobl	astoma 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%			
Liver: Hepatocellular Carcinoma Overall Incidence			1/49 (2%) Mean 0.68%	0/50 (0%) SD 1.18%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
Liver: Hepatocellular Carcinoma,				0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%	Total	0/150 (0%)	Mean 0%	SD 0%			
Liver: Ito Cell Tumor Benign		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	` ,	` '	` '	Total	` '	` '	` ,			
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

Page: 17

			Male			Female			
*Lung: Alveolar/Bronchiolar A	Adenoma								
		1/50 (2%)	2/49 (4%)	0/50 (0%)		4/50 (8%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	3/149 (2.01%)	Mean 2.03%	SD 2.04%	Total	5/150 (3.33%)	Mean 3.33%	SD 4.16%	
Lung: Alveolar/Bronchiolar C	Carcinoma								
		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%	Total	0/150 (0%)	Mean 0%	SD 0%	
Lung: Alveolar/Bronchiolar C Overall Incidence	Carcinoma or Alv	veolar/Bronchiolar Adeno 1/50 (2%) 3/149 (2.01%)	ma 2/49 (4%) Mean 2.03%	0/50 (0%) SD 2.04%	Total	4/50 (8%) 5/150 (3.33%)	0/50 (0%) Mean 3.33%	1/50 (2%) SD 4.16%	
Lung: Fibrosarcoma		0/50 (0%)				0/50 (0%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
Mammary Gland: Adenolipoma	•••••				••••				
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
verall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
Mammary Gland: Adenoma									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 18 Report Date: 06/05/2013

Species: RATS Strain: F 344/N Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male			Female			
#Mammary Gland: Carcinoma									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	
#Mammary Gland: Carcinoma or Adenoma									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	3/50 (6%)	1/50 (2%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	4/150 (2.67%)	Mean 2.67%	SD 3.06%	
#Mammary Gland: Fibroadenoma									
		2/50 (4%)	0/49 (0%)	0/50 (0%)		23/50 (46%)	24/50 (48%)	29/50 (58%)	
Overall Incidence	Total	2/149 (1.34%)	Mean 1.33%	SD 2.31%	Total	76/150 (50.67%)	Mean 50.67%	SD 6.43%	
#Mammary Gland: Fibroma									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
#Mammary Gland: Fibroma, Fibroadenoma o	r Adenoma								
		2/50 (4%)	0/49 (0%)	0/50 (0%)		23/50 (46%)	25/50 (50%)	29/50 (58%)	
Overall Incidence	Total	2/149 (1.34%)	Mean 1.33%	SD 2.31%	Total	77/150 (51.33%)	Mean 51.33%	SD 6.11%	
#Mammary Gland: Fibroma, Fibroadenoma, C	Carcinoma, o		0/49 (0%)	0/50 (0%)		22/50 (469/)	26/50 (52%)	30/50 (60%)	
Overall Incidence	Total	2/50 (4%) 2/149 (1.34%)	0/49 (0%) Mean 1.33%	0/50 (0%) SD 2.31%	Total	23/50 (46%) 79/150 (52.67%)	26/50 (52%) Mean 52.67%	30/50 (60%) SD 7.02%	
Overall illiciation	ı ulaı	2/143 (1.34/0)	IVICALI 1.33/0	۰۰۰۰ ۲.۵۱ <i>/</i> ۵	ı ulal	19/100 (02.01/0)	IVICALI 32.0770	3D 1.02/0	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 19

			Male		Female				
#Mesentery: Fibrous Histiocytoma									
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Mesentery: Schwannoma Malignan	t								
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Nose: Adenoma									
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Oral Cavity (Oral Mucos Papilloma Squamous o	a, Tongue, Phar	ynx, Tooth, Gingiva):							
Overall Incidence	Total	0/50 (0%) 1/149 (0.67%)	1/49 (2%) Mean 0.68%	0/50 (0%) SD 1.18%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	
Oral Cavity (Oral Mucos Squamous Cell Carcino	a, Tongue, Phar					•••••			
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Oral Cavity (Oral Mucos			1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male		Female				
Oral Mucosa: Squamous Cell Carcinom	a								
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Oral Mucosa: Squamous Cell Papilloma	· · · · · · · · · · · · · · · · · · ·		•••••						
verall Incidence	Total	0/50 (0%) 1/149 (0.67%)	1/49 (2%) Mean 0.68%	0/50 (0%) SD 1.18%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Ovary: Cystadenoma									
verall Incidence					Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	
ovary: Fibrosarcoma									
verall Incidence					Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	
Ovary: Granulosa Cell Tumor Be		•••••	•••••					•••••	
verall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
ovary: Granulosa Cell Tumor Ma	lignant								
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 21

			Male			Female				
*Ovary: Granulosa Cell Tumor: Be	nign, Malign	ant, NOS								
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
*Ovary:	Aolianont		•••••							
Granulosa-Theca Tumor M	nangnant					0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%		
*Ovary: Schwannoma Malignant										
						0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%		
*Ovary: Sertoli Cell Tumor Maligna	ant					2/22 /22/	2/20 (201)	2/22 (221)		
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
*Ovary: Tubulostromal Adenoma										
Overall Incidence					Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%		
*Pancreas: Adenoma		2/22	(0.5)	2/22				(201)		
Overall Incidence	Total	0/50 (0%) 1/149 (0.67%)	1/49 (2%) Mean 0.68%	0/50 (0%) SD 1.18%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 22

			Male		Female				
Pancreas: Carcinoma or Adenoma									
Overall Incidence	Total	0/50 (0%) 1/149 (0.67%)	1/49 (2%) Mean 0.68%	0/50 (0%) SD 1.18%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Pancreas: Mixed Tumor Benign									
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Parathyroid Gland: Adenoma									
Overall Incidence	Total	0/47 (0%) 1/145 (0.69%)	1/49 (2%) Mean 0.68%	0/49 (0%) SD 1.18%	Total	1/38 (3%) 1/132 (0.76%)	0/44 (0%) Mean 0.88%	0/50 (0%) SD 1.52%	
Pituitary Gland: Pars Dista Adenoma									
Overall Incidence	Total	38/50 (76%) 82/149 (55.03%)	21/49 (43%) Mean 54.95%	23/50 (46%) SD 18.3%	Total	34/50 (68%) 94/150 (62.67%)	29/50 (58%) Mean 62.67%	31/50 (62%) SD 5.03%	
Pituitary Gland: Pars Dista Carcinoma									
Overall Incidence	Total	0/50 (0%) 1/149 (0.67%)	0/49 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	2/50 (4%) 3/150 (2%)	1/50 (2%) Mean 2%	0/50 (0%) SD 2%	
Pituitary Gland: Pars Dista Carcinoma or Adenoma									
Overall Incidence	Total	38/50 (76%) 83/149 (55.7%)	21/49 (43%) Mean 55.62%	24/50 (48%) SD 17.84%	Total	36/50 (72%) 97/150 (64.67%)	30/50 (60%) Mean 64.67%	31/50 (62%) SD 6.43%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

Route: GAVAGE

Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female			
*Pituitary Gland: Pars Dis Ganglioneuroma	stalis or Unspec	ified Site:							
-		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
*Pituitary Gland: Pars Into Adenoma	ermedia:								
		1/50 (2%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
*Pituitary Gland: Pars Into Carcinoma or Adenoma									
Overall Incidence	Total	1/50 (2%) 1/149 (0.67%)	0/49 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	
Overall incidence	10tai	1/149 (0.67%)			10tai	1/150 (0.67%)	wiean 0.67%		
*Pituitary Gland: Pars Ne Craniopharyngioma	rvosa:								
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
*Prostate: Adenoma									
Occupation of demand	T-1-1	0/50 (0%)	0/49 (0%)	0/50 (0%)					
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%					
*Prostate: Carcinoma or Adenoma	a								
		0/50 (0%)	0/49 (0%)	0/50 (0%)					
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%					

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 24

			Male			Female				
*Salivary Glands: Carcinoma					,					
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (SD 0%	(0%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
*Salivary Glands: Carcinoma or Adenoma				0/70	(001)	•••••	2/20 (201)	2(72 (22))	(00)	
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (SD 0%	(0%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
*Salivary Glands: Sarcoma										
Overall Incidence	Total	0/50 (0%) 1/149 (0.67%)	0/49 (0%) Mean 0.67%	1/50 (SD 1.15%	(2%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
*Salivary Glands: Schwannoma Malignant										
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (SD 0%	(0%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Seminal Vesicle: Adenoma										
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (SD 0%	(0%)					
#Skeletal Muscle: Fibrous Histiocytoma				2/20	(224)	•••••				
Overall Incidence	Total	0/50 (0%) 1/149 (0.67%)	1/49 (2%) Mean 0.68%	0/50 (SD 1.18%	(0%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 25

			Male					Female				
#Skeletal Muscle: Lipoma		0/50 (0%)	0/49 (0%)	0/50 ((0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	(0 %)	Total	0/150 (0%)	Mean 0%	SD 0%			
#Skin: Basal Cell Adenoma		1/50 (2%)	2/49 (4%)		(2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	4/149 (2.68%)	Mean 2.69%	SD 1.2%	(= /3)	Total	0/150 (0%)	Mean 0%	SD 0%			
#Skin: Basal Cell Adenoma or Overall Incidence	Total	1/50 (2%) 4/149 (2.68%)	2/49 (4%) Mean 2.69%	1/50 SD 1.2%	(2%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
#Skin:		Fumor Benign, or Trichoe		1/50	(2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	4/149 (2.68%)	Mean 2.69%	SD 1.2%	(270)	Total	0/150 (0%)	Mean 0%	SD 0%			
#Skin: Basal Cell Carcinoma												
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 SD 0%	(0%)	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%			
#Skin: Basal Cell Carcinoma o	r Basosquamo	us Tumor (malignant or N	OS) 0/49 (0%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)			
		0,00 (0,0)					0,00 (0,0)	3/00 (0/0)	., (= ,,			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

Species: RATS Strain: F 344/N Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

		Male					Female				
#Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma											
		1/50 (2%)	2/49 (4%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	4/149 (2.68%)	Mean 2.69%	SD 1.2%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%			
		na, Basosq. Tumor (M or I eratoacanthoma, Trichoep 2/50 (4%)		na, 4/50 (8%)		1/50 (2%)	0/50 (0%)	2/50 (4%)			
Overall Incidence	Total	8/149 (5.37%)	Mean 5.36%	SD 2.29%	Total	3/150 (2%)	Mean 2%	SD 2%			
∕Skin: Fibroma		1/50 (2%)	7/49 (14%)	6/50 (12%)		1/50 (2%)	1/50 (2%)	1/50 (2%)			
Overall Incidence	Total	14/149 (9.4%)	Mean 9.43%	SD 6.53%	Total	3/150 (2%)	Mean 2%	SD 0%			
Skin: Fibroma, Fibrosarcoma	a, Sarcoma, Myx	oma, Myxosarcoma, or F 2/50 (4%)	ibrous Histiocytoma 7/49 (14%)	6/50 (12%)		1/50 (2%)	1/50 (2%)	4/50 (8%)			
Overall Incidence	Total	15/149 (10.07%)	Mean 10.1%	SD 5.4%	Total	6/150 (4%)	Mean 4%	SD 3.46%			
Skin: Fibrosarcoma		0/50 (00/)	0/40 (00)	0(50 (00))		0/50 (00/)	0/50 (00/)	0(50 (00))			
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 3/150 (2%)	0/50 (0%) Mean 2%	3/50 (6%) SD 3.46%			
······											
Skin: Fibrosarcoma, Sarcom	a, Myxosarcoma	a, or Fibrous Histiocytom 1/50 (2%)	a 0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	3/50 (6%)			
Overall Incidence	Total	1/50 (2%)	0/49 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	3/150 (2%)	0/50 (0%) Mean 2%	3/50 (6%) SD 3.46%			
Overali incidence	iotai	1/149 (0.67%)	iviean 0.67%	SD 1.15%	ıotai	3/150 (2%)	iviean 2%	SD 3.46%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 27

			Male		Female				
#Skin: Fibrous Histiocytoma									
Overall Incidence	Total	1/50 (2%) 1/149 (0.67%)	0/49 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Skin: Hemangiosarcoma									
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Skin: Keratoacanthoma		2/50 //0/)	0/40 /09/	2/50 (69/)		0/50 (0%)	0/50 (0%)	1/50 /29/\	
Overall Incidence	Total	2/50 (4%) 5/149 (3.36%)	0/49 (0%) Mean 3.33%	3/50 (6%) SD 3.06%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	
Skin: Lipoma									
Overall Incidence	Total	0/50 (0%) 1/149 (0.67%)	1/49 (2%) Mean 0.68%	0/50 (0%) SD 1.18%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Skin: Liposarcoma									
Overall Incidence	Total	0/50 (0%) 1/149 (0.67%)	1/49 (2%) Mean 0.68%	0/50 (0%) SD 1.18%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	
Skin: Neural Crest Tumor									
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

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			Male				Female			
#Skin: Neurofibroma or Schwannoma benign										
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
Skin: Neurofibrosarcoma or Sch	nwannoma (m	nalignant or NOS)								
	•	1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%		
Skin: Neurofibrosarcoma, Neuro		Schwannoma (benign, ma	alignant or NOS)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 /00/\		
Suggest to add and a	Tatal	1/50 (2%)	0/49 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%		
Skin: Sarcoma		0/50 /00/	0/40 /00/	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 /00/		
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
	10tai	0/149 (0%)	iviean 0%	3D 0%	ı olal		IVIEAN 076			
≮Skin: Schwannoma Benign		0/50 (09/)	0/40 (0%)	0/50 (09/)		0/50 (09/)	0/50 (0%)	0/50 (09/)		
Overall Incidence	Total	0/50 (0%)	0/49 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
Skin: Schwannoma Malignant										
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

d Control Animal Groups Report Date: 06/05/2013 VAGE

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			Male			Female				
#Skin: Squamous Cell Carcinoma										
O	T-1-1	0/50 (0%)	0/49 (0%)	`	0%) Ta	1/50 (2%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	То	tal 1/150 (0.67%)	Mean 0.67%	SD 1.15%		
#Skin: Squamous Cell Carcinoma or Carcinoma	a, Basal Cell	Carcinoma, Basosquamo	us Tumor (malignant	or NOS),						
		0/50 (0%)	0/49 (0%)	0/50 (0	0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	То	tal 2/150 (1.33%)	Mean 1.33%	SD 1.15%		
#Skin: Squamous Cell Papilloma		0/50 (0%)	0/49 (0%)		J%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	To	tal 0/150 (0%)	Mean 0%	SD 0%		
≇Skin: Squamous Cell Papilloma	or Papilloma	o/50 (0%)	0/49 (0%)	0/50 ((0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	, To	tal 0/150 (0%)	Mean 0%	SD 0%		
#Skin: Squamous Cell Papilloma	, Papilloma, S	Squamous Cell Carcinom	a or Keratoacanthom		6%)	1/50 (2%)	0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	5/149 (3.36%)	Mean 3.33%	SD 3.06%	To	` '	Mean 1.33%	SD 1.15%		
#Skin: Squamous Cell Papilloma		or Keratoacanthoma 2/50 (4%)	0/49 (0%)	3/50 (6	6%)	0/50 (0%)	0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	5/149 (3.36%)	Mean 3.33%	SD 3.06%	To	` '	Mean 0.67%	SD 1.15%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: Trichoepithelioma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Skin: Sebaceous Gland: Adenoma 0/50 (0%)0/49 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/149 (0.67%) Mean 0.67% SD 1.15% 0/150 (0%) Mean 0% SD 0% Total **#Skin: Sebaceous Gland:** Carcinoma or Adenoma 0/50 (0%)0/49 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 1/149 (0.67%) Mean 0.67% SD 1.15% 0/150 (0%) Mean 0% SD 0% Total Total **#Spinal Cord: Glioma Malignant** (2%)0/50 (0%)1/49 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/149 (0.67%) Mean 0.68% SD 1.18% Total 0/150 (0%) Mean 0% SD 0% #Stomach, Glandular: Carcinoma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Stomach, Glandular: Carcinoma or Adenoma

0/50

SD 0%

(0%)

Total

0/50

0/150 (0%)

(0%)

0/50

(0%)

Mean 0%

0/50

SD 0%

(0%)

Total

0/50

0/149 (0%)

(0%)

0/49

Mean 0%

(0%)

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Stomach, Glandular: Sarcoma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% 1/150 (0.67%) Mean 0.67% SD 1.15% Total *Testes: Adenoma 37/50 (74%)37/49 (76%)40/50 (80%) **Overall Incidence** Total 114/149 (76.51%) Mean 76.5% SD 3.12% *Testes: Hemangioma 0/50 (0%)0/49 (0%)1/50 (2%)**Overall Incidence** Total 1/149 (0.67%) Mean 0.67% SD 1.15% *Thymus: Thymoma Benign 1/47 (2%)0/48 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/47 (0%)Overall Incidence Total 1/145 (0.69%) Mean 0.71% SD 1.23% Total 1/147 (0.68%) Mean 0.67% SD 1.15% *Thymus: **Thymoma Malignant** 0/47 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/47 (0%)**Overall Incidence** Total 0/145 (0%) Mean 0% SD 0% Total 0/147 (0%) Mean 0% SD 0% *Thymus: **Thymoma NOS** 0/47 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/47 (0%)**Overall Incidence** Total Mean 0% SD 0% 0/147 (0%) Mean 0% SD 0% 0/145 (0%) Total

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Thymus: Thymoma: Benign, Malignant, NOS 1/47 (2%)0/48 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/47 (0%)Overall Incidence Total 1/145 (0.69%) Mean 0.71% SD 1.23% 1/147 (0.68%) Mean 0.67% SD 1.15% Total *Thyroid Gland: C-Cell: Adenoma 10/50 (20%)8/49 (16%) 11/50 (22%)11/49 (22%)5/50 (10%) 9/49 (18%) **Overall Incidence** Total 29/149 (19.46%) Mean 19.44% SD 2.88% 25/148 (16.89%) Mean 16.94% SD 6.35% Total *Thyroid Gland: C-Cell: Carcinoma 1/50 (2%)0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/49 (0%)**Overall Incidence** Total 1/149 (0.67%) Mean 0.67% SD 1.15% 0/148 (0%) Mean 0% SD 0% Total *Thyroid Gland: C-Cell: Carcinoma or Adenoma 11/50 (22%)8/49 (16%) 11/50 (22%) 11/49 (22%)5/50 (10%) 9/49 (18%) **Overall Incidence** Total 30/149 (20.13%) Mean 20.11% SD 3.28% 25/148 (16.89%) Mean 16.94% SD 6.35% Total *Thyroid Gland: Follicular Cell: Adenoma 2/50 (4%) 1/49 (2%)1/50 (2%)1/49 (2%)1/50 (2%)1/49 (2%)**Overall Incidence** Total 4/149 (2.68%) Mean 2.68% SD 1.14% Total 3/148 (2.03%) Mean 2.03% SD 0.02% *Thyroid Gland: Follicular Cell: Carcinoma 0/50 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/49 (0%)**Overall Incidence** Total SD 0% Mean 0% SD 0% 0/149 (0%) Mean 0% Total 0/148 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male				Female			
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma										
		2/50 (4%)	1/49 (2%)	1/50 (2%)		1/49 (2%)	1/50 (2%)	1/49 (2%)		
Overall Incidence	Total	4/149 (2.68%)	Mean 2.68%	SD 1.14%	Total	3/148 (2.03%)	Mean 2.03%	SD 0.02%		
Tongue: Squamous Cell Carcinoma										
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
#Tongue: Squamous Cell Carcinoma c	or Papillom	na Squamous 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%		
Tongue: Squamous Cell Papilloma		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%		
Tooth: Adamantinoma Malignant										
O	Tatal	0/50 (0%)	0/49 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
Urinary Bladder: Carcinoma										
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 34

			Male		Female				
Urinary Bladder: Carcinoma or Papilloma									
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	
Urinary Bladder: Hemangiosarcoma									
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Urinary Bladder: Papilloma		(05)		(00)			(00)	(00)	
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	
Uterus: Adenoma						0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%	
Uterus: Carcinoma									
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Uterus: Leiomyosarcoma					•••••		- /		
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N Length of Study: CHRONIC Tumor Incidence for Selected Control Animal Groups
Route: GAVAGE
Vehicle: CORN OIL

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Male	•		Female	
#Uterus: Polyp Stromal		2/50 (69/)	7/50 (4.49/)	2/50 (60/)
Overall Incidence	Total	3/50 (6%) 13/150 (8.67%)	7/50 (14%) Mean 8.67%	3/50 (6%) SD 4.62%
#Uterus: Sarcoma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Sarcoma Stromal				
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
#Uterus: Sarcoma Stromal or Polyp Stromal		0/50 (00/)	7/50 (4.40())	0/50 /00/)
Overall Incidence	Total	3/50 (6%) 13/150 (8.67%)	7/50 (14%) Mean 8.67%	3/50 (6%) SD 4.62%
#Uterus: Schwannoma Malignant		(00)		
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
#Vagina: Polyp				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 36

			Male				Female	
#Vagina: Sarcoma						0/50 (00)	0/50 (00())	0/50 (00)
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Vagina: Schwannoma Malignant								
Overall Incidence					Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Zymbal's Gland: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Zymbal's Gland: Carcinoma		4/50 (00)	0/40 /00/	0/50 (00/)		0/50 (00)	0/50 (00())	0/50 (00)
Overall Incidence	Total	1/50 (2%) 1/149 (0.67%)	0/49 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Zymbal's Gland: Carcinoma or Adenoma		4/50 (00)	0/40 /00/	0/50 (00/)		0/50 (00)	0/50 (00())	0/50 (00)
Overall Incidence	Total	1/50 (2%) 1/149 (0.67%)	0/49 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

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Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical			
Male										
Southern Research Institute	059903705	06/09/03	729	50(3)	27(662)	523.0	alpha/beta Thujone mixture			
					Female					
Southern Research Institute	059903705	06/09/03	730	50(5)	35(689)	335.4	alpha/beta Thujone mixture			

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: METHYLCELLULOSE

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			Male			Female			
#All Organs: Benign Tumors									
		44/50 (88%)				46/50 (92%)			
Overall Incidence	Total	44/50 (88%)	Mean 88%	SD 0%	Total	46/50 (92%)	Mean 92%	SD 0%	
#All Organs: Malignant Tumors									
		31/50 (62%)				20/50 (40%)			
Overall Incidence	Total	31/50 (62%)	Mean 62%	SD 0%	Total	20/50 (40%)	Mean 40%	SD 0%	
#All Organs: Malignant and Benign T	umors								
		48/50 (96%)				49/50 (98%)			
Overall Incidence	Total	48/50 (96%)	Mean 96%	SD 0%	Total	49/50 (98%)	Mean 98%	SD 0%	
#All Organs: Hemangioma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#All Organs: Hemangiosarcoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#All Organs: Hemangiosarcoma or H	emangioma								
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female			
#All Organs: Histiocytic Sarcoma										
		1/50 (2%)				0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#All Organs:										
Leukemia: Lymphocytic	c, Monocytic, Mo	ononuclear, or Undifferen	ntiated			(0.00)				
		22/50 (44%)				10/50 (20%)				
Overall Incidence	Total	22/50 (44%)	Mean 44%	SD 0%	Total	10/50 (20%)	Mean 20%	SD 0%		
#All Organs:										
•	Histiocytic, Lym	phocytic, Mixed, NOS, or	Undifferentiated Ce	ell Type						
		0/50 (0%)		• •		1/50 (2%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
#All Organs:			•••••							
#All Organs:						0/50 (0%)				
#All Organs:			Mean 4%	SD 0%	Total		Mean 0%	SD 0%		
#All Organs: Mesothelioma: Benign,	Malignant, NOS	2/50 (4%)				0/50 (0%)				
#All Organs: Mesothelioma: Benign, Overall Incidence	Malignant, NOS	2/50 (4%)				0/50 (0%)				
#All Organs: Mesothelioma: Benign, Overall Incidence #All Organs:	Malignant, NOS	2/50 (4%)				0/50 (0%)				
#All Organs: Mesothelioma: Benign, Overall Incidence #All Organs:	Malignant, NOS	2/50 (4%) 2/50 (4%)				0/50 (0%) 0/50 (0%)				
#All Organs: Mesothelioma: Benign, Overall Incidence #All Organs: Mesothelioma: Maligna Overall Incidence #All Organs:	Malignant, NOS Total nt	2/50 (4%) 2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#All Organs: Mesothelioma: Benign, Overall Incidence #All Organs: Mesothelioma: Maligna Overall Incidence	Malignant, NOS Total nt	2/50 (4%) 2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

#All Organs: Osteosarcoma

#All Organs:

Overall Incidence

Overall Incidence

*Adrenal Cortex: Adenoma

Overall Incidence

*Adrenal Cortex: Carcinoma

Overall Incidence

*Adrenal Medulla:

Overall Incidence

Overall Incidence

*Adrenal Medulla:

.....

Osteosarcoma or Osteoma

.....

Pheochromocytoma Benign

Pheochromocytoma Complex

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Male **Female** 1/50 (2%)1/50 (2%)1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) Mean 2% SD 0% 1/50 (2%)1/50 (2%)1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) Mean 2% SD 0% 1/50 (2%)1/47 (2%)1/50 (2%) Mean 2% SD 0% Total 1/47 (2.13%) Mean 2.13% SD 0% 0/50 (0%)0/47 (0%)0/50 (0%) Mean 0% SD 0% Total 0/47 (0%) Mean 0% SD 0% 6/50 (12%)2/48 (4%)6/50 (12%) Mean 12% SD 0% Total 2/48 (4.17%) Mean 4.17% SD 0%

1/48

Total

1/48 (2.08%)

(2%)

Mean 2.08%

SD 0%

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Report Date: 06/05/2013

Total

Total

Total

Total

Total

Total

0/50

0/50 (0%)

(0%)

Mean 0%

SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F 344/N

Toxicology Data Management System

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Mean 2%

SD 0%

Report Date: 06/05/2013

Contract/Lab: All Laboratories

Species: RATS

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRON	NIC											
			Male			Female						
*Adrenal Medulla: Pheochromocytoma Malignant												
•	· ·	0/50 (0%)				0/48 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%				
*Adrenal Medulla: Pheochromocytoma: E	Benign, Complex,	, Malignant, NOS 6/50 (12%)				3/48 (6%)						
Overall Incidence	Total	6/50 (12%)	Mean 12%	SD 0%	Total	3/48 (6.25%)	Mean 6.25%	SD 0%				
#Blood Vessel: Leiomyosarcoma		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Bone: Chordoma		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Bone: Osteoma		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Bone: Osteosarcoma		1/50 (2%)				1/50 (2%)						

SD 0%

1/50 (2%)

Total

Total

1/50 (2%)

Mean 2%

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Bone: Osteosarcoma or Osteoma								
		1/50 (2%	b)			1/50 (2%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Brain: Glioma								
		0/50 (0%	5)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Glioma Benign		0/50 (00/	`			0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		, ,				, ,		
*Brain: Glioma Malignant		0/50 (00/	,			4/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Brain: Oligodendroglioma, Glioma,								
	•	0/50 (0%	o)			1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Brain: Osteosarcoma								
		0/50 (0%	,			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Clitoral/Preputial Gland: Adenoma								
		2/49 (4%)				12/50 (24%)		
Overall Incidence	Total	2/49 (4.08%)	Mean 4.08%	SD 0%	Total	12/50 (24%)	Mean 24%	SD 0%
*Clitoral/Preputial Gland: Carcinoma								
		1/49 (2%)				2/50 (4%)		
Overall Incidence	Total	1/49 (2.04%)	Mean 2.04%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
*Clitoral/Preputial Gland: Carcinoma or Adenoma		2/40 /69/\				44/50 (200/)		
Overall Incidence	Total	3/49 (6%) 3/49 (6.12%)	Mean 6.12%	SD 0%	Total	14/50 (28%) 14/50 (28%)	Mean 28%	SD 0%
		, ,						
*Clitoral/Preputial Gland: Sarcoma		0/49 (0%)				0/50 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Ear: Neural Crest Tumor	•••••							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Eye: Melanoma Benign		0/50 /02/				0/50 (00/)		
Overall Incidence	Total	0/50 (0%)	Maan 00/	CD 00/	Total	0/50 (0%)	Maan OO/	CD 00/
Overali incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Eye: Melanoma Malignant								
-		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Harderian Gland: Adenoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma								
		0/50 (0%)		05.00/		0/50 (0%)		05 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma or Adenoma								
		0/50 (0%)	• • • • • • • • • • • • • • • • • • • •	05.00/		0/50 (0%)		05 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Benign								
		2/50 (4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Malignant								
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Strain: F 344/N Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Intestine Large: Colon/Rectu Adenoma	m:							
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Intestine Large: Colon/Rectu Carcinoma or Adenoma						4/50 (00)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Intestine Small: Duodenum: Leiomyoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Schwannoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Adenoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma		0/50 /00/				0/50 (00/)		
Overall Insidence	Tatal	0/50 (0%)	Mann 00/	CD 00/	Tatal	0/50 (0%)	Mann 00/	CD 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Mean 0%

SD 0%

Report Date: 06/05/2013

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Intestine Small: Jejunum: Leiomyoma 0/50 (0%)0/50 (0%)0/50 (0%) **Overall Incidence** Total Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Intestine Small: Jejunum: Leiomyosarcoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified: Adenoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified: Carcinoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified: Leiomyoma 0/50 (0%)0/50 (0%)

SD 0%

Total

0/50 (0%)

Total

0/50 (0%)

Mean 0%

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N Length of Study: CHRONIC

Leiomyosarcoma

Overall Incidence

Overall Incidence

*Islets, Pancreatic: Adenoma

Overall Incidence

*Islets, Pancreatic: Carcinoma

Overall Incidence

*Islets, Pancreatic:

#Intestine Small: Site Unspecified:

#Intestine Small: Site Unspecified: Schwannoma Malignant

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: METHYLCELLULOSE

Male **Female** 0/50 (0%)Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%)Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% 1/49 (2%)Mean 2% SD 0% Total 1/49 (2.04%) Mean 2.04% SD 0% 0/49 (0%)

0/49 (0%)

Total

Page: 47

Mean 0%

SD 0%

Report Date: 06/05/2013

Carcinoma	or	Adenoma	

.....

3/50 (6%) 1/49 (2%)

Overall Incidence Total 3/50 (6%) Mean 6% SD 0% Total 1/49 (2.04%)

Mean 4%

0/50

0/50 (0%)

0/50

0/50 (0%)

1/50

1/50 (2%)

2/50

2/50 (4%)

Total

Total

Total

Total

*: Denominator is number of animals with tissues examined microscopically

(0%)

(0%)

(2%)

(4%)

 Overall Incidence
 Total
 3/50 (6%)
 Mean 6%
 SD 0%
 Total
 1/49 (2.04%)
 Mean 2.04%
 SD 0%

*Kidney: Pelvis and Transitional Epithelium:

Papilloma

0/48 (0%) 0/48 (0%) Mean 0% SD 0% Total 0/44 (0%)

SD 0%

 Overall Incidence
 Total
 0/48 (0%)
 Mean 0%
 SD 0%
 Total
 0/44 (0%)
 Mean 0%
 SD 0%

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Kidney: Renal Tubule: Adenoma								
		0/48 (0%)				0/44 (0%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/44 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma								
Overall Incidence	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	Total	0/44 (0%) 0/44 (0%)	Mean 0%	SD 0%
					ı Olai			
*Kidney: Renal Tubule: Carcinoma or Adenoma		0/48 (0%)				0/44 (0%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/44 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Lipoma		0/48 (0%)				0/44 (0%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/44 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Mesenchymal Tumor Malig								
		0/48 (0%)				1/44 (2%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	1/44 (2.27%)	Mean 2.27%	SD 0%
*Kidney: Renal Tubule: Sarcoma								
		0/48 (0%)		05.00/		0/44 (0%)		05 00/
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/44 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: METHYLCELLULOSE Report Date: 06/05/2013

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				Mal	e			Female	
*Liver: Hepatocellular Adenoma	ı	,							
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
	ı olal	0/50 (0%)		iviean 0%	3D 0%		0/50 (0%)	wiean 0%	טע עאַ טיי
*Liver: Hepatocellular Carcinom	ıa								
			(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinom	a or Hepatobla		(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	` ,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinom		lular Adenoma	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	` ,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinom		ar Adenoma, or					0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(0,0)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Ito Cell Tumor Benign		1/50	(2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	(= /0)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female		
*Lung: Alveolar/Bronchiolar A	Adenoma								
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Lung: Alveolar/Bronchiolar C									
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
		eolar/Bronchiolar Adenor 2/50 (4%)				0/50 (0%)			
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Lung: Fibrosarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Mammary Gland: Adenolipoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Mammary Gland: Adenoma									
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: METHYLCELLULOSE

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			Male				Female	
#Mammary Gland: Carcinoma								
		0/50 (0%)			2/50 (4%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)			3/50 (6%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%
#Mammary Gland: Fibroadenoma								
O	T-1-1	3/50 (6%	,	OD 00/	T-1-1	26/50 (52%)	Maria 500/	00 00/
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	26/50 (52%)	Mean 52%	SD 0%
Mammary Gland: Fibroma								
Overall Incidence	Total	0/50 (0% 0/50 (0%)) Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
		` ,				` '		
#Mammary Gland: Fibroma, Fibroadenoma or	Adenoma							
		3/50 (6%)			28/50 (56%)		
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	28/50 (56%)	Mean 56%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma, Ca		Adenoma						
Overell lesidence	Tatal	3/50 (6%	,	CD 00/	Tatal	30/50 (60%)	Mana C00/	CD 00/
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	30/50 (60%)	Mean 60%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for

Species: RATS

Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Mesentery: Fibrous Histiocytoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mesentery: Schwannoma Malignan	nt							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Nose: Adenoma								
O	T-1-1	0/50 (0%)	M 00/	OD 00/	T-1-1	0/50 (0%)	M 00/	OD 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Papilloma Squamous o		nx, Tooth, Gingiva):						
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcino	a, Tongue, Phary							
•		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos	a, Tongue, Phary					0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Oral Mucosa: Squamous Cell Carcinoma	1							
·		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Mucosa: Squamous Cell Papilloma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Cystadenoma						0/50 (00/)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Fibrosarcoma Overall Incidence					Tatal	0/50 (0%)	M 00/	CD ov
					Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor Ber	nign					0/50 (00/)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor Mal	ignant							
						1/50 (2%)		05 00/
Overall Incidence					Total	1/50 (2%)	Mean 2%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F 344/N

Toxicology Data Management System

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(0%)

Mean 0%

0/49

0/49 (0%)

Total

Report Date: 06/05/2013

SD 0%

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups Route: GAVAGE

Vehicle: METHYLCELLULOSE

	Male			Female Mean 2% SD 0% Mean 0% SD 0%			
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS							
			1/50 (2%)				
Overall Incidence		Total	1/50 (2%)				
*Ovary:							
Granulosa-Theca Tumor Malignant			- ()				
Occupation of the second		T-1-1	0/50 (0%)	M 00/	00.00/		
Overall Incidence		Total	0/50 (0%)				
Ovary:							
Schwannoma Malignant							
		.	0/50 (0%)		00.00/		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%		
Ovary: Sertoli Cell Tumor Malignant							
Serion Gen Tumor manghant			0/50 (0%)				
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%		
				•••••			
Ovary: Tubulostromal Adenoma							
i ubulostromai Adenoma			0/50 (0%)				
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%		
*Pancreas:							
Adenoma							

SD 0%

Total

(0%)

Mean 0%

0/50

0/50 (0%)

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Pancreas: Carcinoma or Adenoma								
		0/50 (0%)				0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Pancreas: Mixed Tumor Benign								
		1/50 (2%)				0/49 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Parathyroid Gland: Adenoma		0/40 (00/)				0/47 (00/)		
Overall Incidence	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%
Overall incidence		, ,				, ,		
*Pituitary Gland: Pars Distal Adenoma	is or Unspeci	fied Site:						
		24/50 (48%)				25/50 (50%)		
Overall Incidence	Total	24/50 (48%)	Mean 48%	SD 0%	Total	25/50 (50%)	Mean 50%	SD 0%
*Pituitary Gland: Pars Distal Carcinoma			•••••					
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Pituitary Gland: Pars Distal Carcinoma or Adenoma		fied Site:						
		24/50 (48%)				26/50 (52%)		
Overall Incidence	Total	24/50 (48%)	Mean 48%	SD 0%	Total	26/50 (52%)	Mean 52%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Species: RATS **Strain:** F 344/N

Length of Study: CHRONIC

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			Male				Female		
*Pituitary Gland: Pars Distal Ganglioneuroma	lis or Unspeci	fied Site:							
J		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
*Pituitary Gland: Pars Intern Adenoma									
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
*Pituitary Gland: Pars Intern Carcinoma or Adenoma									
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
*Pituitary Gland: Pars Nervo Craniopharyngioma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Prostate: Adenoma									
		2/50 (4%)							
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%					
*Prostate: Carcinoma or Adenoma		2/50 (4%)							
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%					
Jveran illelueliee	illai	2/30 (4/0)	IVICALI 4/0	3D 0/0					

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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Report Date: 06/05/2013

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%		
*Salivary Glands: Carcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma		0(50 (00))				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
*Salivary Glands: Sarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%
*Salivary Glands: Schwannoma Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Fibrous Histiocytoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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				Male				Female	
#Skeletal Muscle: Lipoma									
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma									
		1/50	(2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Basal Cell Adenoma or E	Basosquamous	Tumor Benign 1/50	(2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Basal Cell Adenoma, Bas		ımor Benign, oı					1/50 (2%)		
Overall Incidence	Total	3/50 (6%)	, ,	Mean 6%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Basal Cell Carcinoma									
		1/50	(2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Basal Cell Carcinoma or	Basosquamou	s Tumor (malig					1/50 (2%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

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			Male				Female					
#Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli		oma, Basosquamous Tui	mor (benign, maligna	nt or								
		4/50 (8%)				2/50 (4%)						
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%				
#Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma 9/50 (18%) 2/50 (4%) Overall Incidence Total 9/50 (18%) SD 0% Total 9/50 (18%) SD 0% Total 9/50 (18%) SD 0%												
Overall Incidence	Total	9/50 (18%)	Mean 18%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%				
#Skin: Fibroma		11/50 (22%)				2/50 (4%)						
Overall Incidence	Total	11/50 (22%)	Mean 22%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%				
#Skin: Fibroma, Fibrosarcoma Overall Incidence	a, Sarcoma, Myxo	oma, Myxosarcoma, or F 16/50 (32%) 16/50 (32%)	ibrous Histiocytoma Mean 32%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%				
#Skin: Fibrosarcoma		3/50 (6%)				0/50 (0%)						
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skin: Fibrosarcoma, Sarcom	a, Myxosarcoma	, or Fibrous Histiocytom 6/50 (12%)	a			0/50 (0%)						
Overall Incidence	Total	6/50 (12%)	Mean 12%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Skin: Fibrous Histiocytoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Hemangiosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Keratoacanthoma								
Overall Incidence	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Lipoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor		0(50 (00))				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male			Female				
#Skin: Neurofibroma or Schwan	noma benign									
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin:										
Neurofibrosarcoma or Sc	hwannoma (m	0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Neurofibrosarcoma, Neur				•••••			•••••			
Neuronbrosarcoma, Neur	onbroma, or o	0/50 (0%)	ingriant or NOS)			0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Sarcoma										
		3/50 (6%)				0/50 (0%)				
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Schwannoma Benign										
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Schwannoma Malignant										
Occupation of the second	T-1-1	0/50 (0%)	M 00/	OD 00/	T-1-1	0/50 (0%)	Maran 00/	OD 00/		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Skin: Squamous Cell Carcine	oma							
•		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcine or Carcinoma	oma, Basal Cell (Carcinoma, Basosquamo	us Tumor (malignan	t or NOS),				
		1/50 (2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Squamous Cell Papillo		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillo	ma or Papilloma					0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillo	ma, Papilloma, S	Squamous Cell Carcinoma 5/50 (10%)	a or Keratoacanthon	na		0/50 (0%)		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillo	ma, Papilloma, o	or Keratoacanthoma 5/50 (10%)				0/50 (0%)		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F 344/N

Toxicology Data Management System

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Report Date: 06/05/2013

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups **Route:** GAVAGE

Vehicle: METHYLCELLULOSE

			Male				Female	
#Skin: Trichoepithelioma						, , , , , , , , , , , , , , , , , , ,		
·		2/50 (4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma								
		0/50 (0%)		05.00/		0/50 (0%)		05 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%)		05.00/		0/50 (0%)		05 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Spinal Cord: Glioma Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma		•••••						
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male			Female			
#Stomach, Glandular: Sarcoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Testes: Adenoma									
		35/50 (70%)							
Overall Incidence	Total	35/50 (70%)	Mean 70%	SD 0%					
*Testes: Hemangioma									
Overall Insidence	Tatal	0/50 (0%)	Mann 00/	CD 00/					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%					
*Thymus: Thymoma Benign		0/44 (0%)				0/48 (0%)			
Overall Incidence	Total	0/44 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%	
*Thymus: Thymoma Malignant									
		0/44 (0%)				0/48 (0%)			
Overall Incidence	Total	0/44 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%	
*Thymus: Thymoma NOS									
		0/44 (0%)				0/48 (0%)			
Overall Incidence	Total	0/44 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Report Date: 06/05/2013

SD 0%

Mean 0%

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

			Male				Female				
*Thymus: Thymoma: Benign, Malignant, NOS 0/44 (0%) 0/48 (0%)											
Overall Incidence	Total	0/44 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%			
'Thyroid Gland: C-Cell: Adenoma											
		6/46 (13%)				4/42 (10%)					
Overall Incidence	Total	6/46 (13.04%)	Mean 13.04%	SD 0%	Total	4/42 (9.52%)	Mean 9.52%	SD 0%			
*Thyroid Gland: C-Cell: Carcinoma		0/46 (0%)				3/42 (7%)					
Overall Incidence	Total	0/46 (0%)	Mean 0%	SD 0%	Total	3/42 (7.14%)	Mean 7.14%	SD 0%			
Thyroid Gland: C-Cell: Carcinoma or Adenoma		6/46 (13%)				7/42 (17%)					
Overall Incidence	Total	6/46 (13.04%)	Mean 13.04%	SD 0%	Total	7/42 (16.67%)	Mean 16.67%	SD 0%			
Thyroid Gland: Follicular Cel Adenoma	l:										
		0/46 (0%)				0/42 (0%)					
Overall Incidence	Total	0/46 (0%)	Mean 0%	SD 0%	Total	0/42 (0%)	Mean 0%	SD 0%			
*Thyroid Gland: Follicular Cel Carcinoma	l:	0/46 (09/)				0/42 (09/)					
		0/46 (0%)				0/42 (0%)					

SD 0%

0/42 (0%)

Total

Total

0/46 (0%)

Mean 0%

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Page: 66

			Male				Female	
*Thyroid Gland: Follicular Ce Carcinoma or Adenoma	ell:							
Overall Incidence	Total	0/46 (0%) 0/46 (0%)	Mean 0%	SD 0%	Total	0/42 (0%) 0/42 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma	 1							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma	or Papilloma	ı Squamous 0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tooth: Adamantinoma Malignant						(004)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Carcinoma		0/50 (0%)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 67

Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Urinary Bladder: Carcinoma or Papilloma								
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 00/	Total	0/50 (0%)	Maan 09/	SD 0%
Overall incidence	Total	0/50 (0%)	wiean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	งบ บ _%
*Urinary Bladder: Hemangiosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Papilloma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Adenoma						0/50 (004)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Carcinoma								
						0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Leiomyosarcoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence fo

Contract/Lab: All Laboratorie
Species: RATS

Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: METHYLCELLULOSE

Page: 68

	Male		Female			
#Uterus: Polyp Stromal						
Overall Incidence	To		17/50 (34%) 17/50 (34%)	Mean 34%	SD 0%	
#Uterus: Sarcoma						
Overall Incidence		otal	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Sarcoma Stromal						
Overall Incidence	To	otal	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Sarcoma Stromal or Polyp Stromal						
Overall Incidence		otal '	17/50 (34%) 17/50 (34%)		SD 0%	
#Uterus: Schwannoma Malignant						
Overall Incidence	To	otal	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Vagina: Polyp						
Overall Incidence	To	otal	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: METHYLCELLULOSE

Page: 69

			Male				Female	
#Vagina: Sarcoma						0/50 (00/)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Vagina: Schwannoma Malignant								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma		0/50 (09/)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 70

Report Date: 06/05/2013

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory	052000505	01/21/04	727	50(3)	30(679)	498.5	Ginseng
					Female		
Battelle Columbus Laboratory	052000505	01/22/04	728	50(5)	36(700)	355.0	Ginseng

Species: RATS

Toxicology Data Management System

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Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Strain: F 344/N Vehicle: WATER

			Male				Female	
#All Organs: Benign Tumors		40/E0 (000/)				42/50 (049/)		
Overall Incidence	Total	49/50 (98%) 49/50 (98%)	Mean 98%	SD 0%	Total	42/50 (84%) 42/50 (84%)	Mean 84%	SD 0%
#All Organs: Malignant Tumors								
Overall Incidence	Total	26/50 (52%) 26/50 (52%)	Mean 52%	SD 0%	Total	10/50 (20%) 10/50 (20%)	Mean 20%	SD 0%
		, ,				` ,		
#All Organs: Malignant and Benign Tui	mors	49/50 (98%)				45/50 (90%)		
Overall Incidence	Total	49/50 (98%)	Mean 98%	SD 0%	Total	45/50 (90%)	Mean 90%	SD 0%
#All Organs: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma or Her	nangioma							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Date

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 72

			Male				Female	
#All Organs: Histiocytic Sarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs:	c Managytic Ma	ononuclear, or Undifferer	ntiated					
Leukeilla. Lymphocyti	c, worldcytic, wic	18/50 (36%)	ilialeu			6/50 (12%)		
Overall Incidence	Total	18/50 (36%)	Mean 36%	SD 0%	Total	6/50 (12%)	Mean 12%	SD 0%
#All Organs:								
Malignant Lymphoma:	Histiocytic, Lym	phocytic, Mixed, NOS, or 0/50 (0%)	Undifferentiated Ce	II Туре		0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs:								
#All Organs:			Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Benign, Overall Incidence #All Organs:	Malignant, NOS	2/50 (4%)				0/50 (0%)		
#All Organs: Mesothelioma: Benign, Overall Incidence	Malignant, NOS	2/50 (4%) 2/50 (4%)				0/50 (0%) 0/50 (0%)		
#All Organs: Mesothelioma: Benign, Overall Incidence #All Organs: Mesothelioma: Maligna	Malignant, NOS Total	2/50 (4%) 2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Benign, Overall Incidence #All Organs:	Malignant, NOS	2/50 (4%) 2/50 (4%)				0/50 (0%) 0/50 (0%)		
#All Organs: Mesothelioma: Benign, Overall Incidence #All Organs: Mesothelioma: Maligna	Malignant, NOS Total	2/50 (4%) 2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Benign, Overall Incidence #All Organs: Mesothelioma: Maligna Overall Incidence #All Organs:	Malignant, NOS Total	2/50 (4%) 2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 73

				Male				Female	
#All Organs: Osteosarcoma									
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma or Osteoma		1/50	(20/)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Adenoma		0/50	(00()				0/50 (00/)		
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Carcinoma		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Benign									
Overall Incidence	Total	4/50 4/50 (8%)	(8%)	Mean 8%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Adrenal Medulla: Pheochromocytoma Comple	ex	0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(370)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 74

				Male				Female			
*Adrenal Medulla: Pheochromocytoma Malignant											
·	· ·	0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Adrenal Medulla: Pheochromocytoma: B											
	J., J., J.,		8%)				1/50 (2%)				
Overall Incidence	Total	4/50 (8%)	,,	Mean 8%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
#Blood Vessel: Leiomyosarcoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	U70)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Bone: Chordoma			0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Bone: Osteoma											
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Bone: Osteosarcoma		4/50	201)				0/50 (00/)				
Overell Insidence	Tatal		2%)	Mana 20/	CD 00/	Tatal	0/50 (0%)	Mann 00/	CD 00/		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 75

				Male				Female			
#Bone: Osteosarcoma or Osteoma											
Overall Incidence	Total	1/50 (2 1/50 (2%)	2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
		1/30 (2/8)	ا								
*Brain: Glioma											
		,	0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	ſ	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Brain: Glioma Benign		0/50 //	00()				0/50 (00/)				
Overall Incidence	Total	0/50 (0 0/50 (0%)	0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
		, ,					` '				
*Brain: Glioma Malignant		0/50 (0	0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	ĺ	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Brain: Oligodendroglioma, Glioma											
			0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	ľ	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Brain: Osteosarcoma		0/50 ((0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
	ı Ulai	0/30 (0%)	ا	vicaii U/0	0/0 ط	ı ulal	0/00 (0/0)	IVICALL U/0	0 / 0 ط		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 76

			Male				Female			
*Clitoral/Preputial Gland: Adenoma										
		0/50 (0%)				1/50 (2%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
*Clitoral/Preputial Gland: Carcinoma										
		0/50 (0%)				1/50 (2%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
*Clitoral/Preputial Gland: Carcinoma or Adenoma		0/50 (004)				0/50 (404)				
Occasional descriptions of	T-1-1	0/50 (0%)	M 00/	OD 00/	Tatal	2/50 (4%)	M 40/	OD 00/		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%		
*Clitoral/Preputial Gland: Sarcoma										
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Ear: Neural Crest Tumor										
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Eye: Melanoma Benign										
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 77

			Male				Female	
#Eye: Melanoma Malignant		0/50 (00)				4/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Harderian Gland: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma		4/50 (20()				0/50 (09/)		
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma or Adenoma		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Benign								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 78

			Male			Female					
#Intestine Large: Colon/Rectum: Adenoma											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Intestine Large: Colon/Rec Carcinoma or Adenoma											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Intestine Small: Duodenur Leiomyoma						1/50 (20/)					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%			
#Intestine Small: Duodenur Schwannoma Malignant		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Intestine Small: Ileum: Adenoma		•••••									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Intestine Small: Jejunum: Carcinoma		4/50 (00)				0/50 (00/)					
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page**: 79

			Male				Female	
#Intestine Small: Jejunum: Leiomyoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma	•••••							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Carcinoma								
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Carcinoma or Adenoma				•••••				
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Leiomyoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 80

Report Date: 06/05/2013

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Vehicle: WATER

Route: GAVAGE

Length of Study: CHRONIC

Male **Female** #Intestine Small: Site Unspecified: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/50 (0%) **Overall Incidence** Total Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified: **Schwannoma Malignant** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Islets, Pancreatic: Adenoma 0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 1/50 (2%) Mean 2% SD 0% *Islets, Pancreatic: Carcinoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total Mean 0% SD 0% 0/50 (0%) *Islets, Pancreatic: Carcinoma or Adenoma 0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 1/50 (2%) Mean 2% SD 0% *Kidney: Pelvis and Transitional Epithelium: **Papilloma** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 81

				Male				Female	
*Kidney: Renal Tubule: Adenoma									
Overall Incidence	Total	1/50 (2%)	2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma									
Overall Incidence	Total	1/50 (2%)	2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma		2/50 (-	4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	,	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Lipoma		0/50 (0%)			Total	0/50 (0%)	M 00/	OD 00
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Mesenchymal Tumor Malig	jnant								
Overall Incidence	Total	0/50 (0%)	0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Sarcoma		0/50 //	00/)				0/50 /09/		
Overall Incidence	Total	0/50 (0%)	0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 82

			Male				Female				
*Liver: Hepatocellular Adenoma 0/50 (0%) 0/50 (0%) 0/50 (0%)											
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Liver: Hepatocellular Carcinoma	a	1/50 (2%)				0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Liver: Hepatocellular Carcinoma						0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Liver: Hepatocellular Carcinoma						0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Liver: Hepatocellular Carcinoma						0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Liver: Ito Cell Tumor Benign		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 83

*Lung:			Male		Female						
*Lung: Alveolar/Bronchiolar Adenoma											
		0/50 (0%)				1/50 (2%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%			
*Lung: Alveolar/Bronchiolar Carc	inoma										
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Lung: Alveolar/Bronchiolar Carc Overall Incidence	inoma or Alve	olar/Bronchiolar Adeno 0/50 (0%) 0/50 (0%)	ma Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%			
Overall incluence		, ,				, ,		3D 0%			
*Lung: Fibrosarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
		0/50 (0%)		3D 0%	ı olal	0/50 (0%)	wiean 0%	3D 0%			
#Mammary Gland: Adenolipoma											
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Mammary Gland: Adenoma		0/50 (09/)				2/50 (49/)					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 84

			Male				Female	
#Mammary Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
#Mammary Gland: Fibroadenoma		2/50 (4%)				22/50 (649/)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	32/50 (64%) 32/50 (64%)	Mean 64%	SD 0%
#Mammary Gland: Fibroma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma or								
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	33/50 (66%) 33/50 (66%)	Mean 66%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma, C	arcinoma, or	Adenoma 2/50 (4%)				33/50 (66%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	33/50 (66%)	Mean 66%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 85

			Male				Female	
#Mesentery: Fibrous Histiocytoma								
	+	0/50 (0%)		OD .00/	T	0/50 (0%)		00.004
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mesentery: Schwannoma Malignar	nt							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Nose: Adenoma		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Oral Cavity (Oral Mucos Papilloma Squamous o Overall Incidence	a, Tongue, Phary		Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcine								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos	a, Tongue, Phary					0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Oral Mucosa: Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%) SD 0% **Overall Incidence** Total Mean 0% SD 0% Total 0/50 (0%) Mean 0% **#Oral Mucosa: Squamous Cell Papilloma** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Ovary: Cystadenoma 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% *Ovary: Fibrosarcoma 0/50 (0%)SD 0% **Overall Incidence** Total 0/50 (0%) Mean 0% *Ovary: **Granulosa Cell Tumor Benign** 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% **Granulosa Cell Tumor Malignant** 0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% 0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

Page: 87

Report Date: 06/05/2013

SD 0%

Mean 0%

		Female	
Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
Total	0/50 (0%)	Mean 0%	SD 0%
Total	0/50 (0%)	Mean 0%	SD 0%
	0/50 (0%)		
Total	0/50 (0%)	Mean 0%	SD 0%
Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
	Total Total Total	Total 0/50 (0%) O/50 (0%) Total 0/50 (0%) O/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%)	0/50 (0%) Total 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)

SD 0%

0/50 (0%)

Total

Total

0/50 (0%)

Mean 0%

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 88

			Male				Female	
*Pancreas: Carcinoma or Adenoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Pancreas: Mixed Tumor Benign								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Parathyroid Gland: Adenoma		0/50 (00)				0/40 (00)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%
Overall incluence		0/50 (0%)				0/48 (0%)		3D 0%
*Pituitary Gland: Pars Dista Adenoma	is or Unspeci	ified Site:						
		20/50 (40%)				16/50 (32%)		
Overall Incidence	Total	20/50 (40%)	Mean 40%	SD 0%	Total	16/50 (32%)	Mean 32%	SD 0%
*Pituitary Gland: Pars Dista Carcinoma			•••••					
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Dista Carcinoma or Adenoma		ified Site:						
		20/50 (40%)				16/50 (32%)		
Overall Incidence	Total	20/50 (40%)	Mean 40%	SD 0%	Total	16/50 (32%)	Mean 32%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

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Report Date: 06/05/2013

Species: RATS **Strain:** F 344/N

Length of Study: CHRONIC

Route: GAVAGE Vehicle: WATER

		Male				Female	
is or Unspecif	ied Site:						
	0/50 (0%)				0/50 (0%)		
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
nedia:							
	` '				` '		
	` '	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
nedia:	0/50 (09/)				0/50 (09/)		
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
sa:	0/50 (00/)				0/50 (00/)		
Total	` ,	Moon 0%	SD 0%	Total	` '	Moon 0%	SD 0%
	, ,						
	` '						
	` '						
Total	` ,	Mean 2%	SD 0%				
1	Total nedia: Total nedia: Total ssa: Total Total	Total 0/50 (0%) nedia: 0/50 (0%) Total 0/50 (0%) nedia: 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 1/50 (2%) Total 1/50 (2%)	is or Unspecified Site: 0/50 (0%)	is or Unspecified Site: 0/50 (0%)	is or Unspecified Site: 10/50	is or Unspecified Site: O/50 (0%)	is or Unspecified Site: 0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 90 Report Date: 06/05/2013

Species: RATS Strain: F 344/N Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male	-			Female	
*Salivary Glands: Carcinoma	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		` ,				` ,	ivican 076	
*Salivary Glands: Sarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: Schwannoma Malignant Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
			iviean 0%			0/30 (0%)	iviean 0%	
#Seminal Vesicle: Adenoma Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%				
#Skeletal Muscle: Fibrous Histiocytoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 91

				Male				Female	
#Skeletal Muscle: Lipoma									
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma									
		1/50	(2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Basal Cell Adenoma or I	3asosquamous	1/50	(2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Basal Cell Adenoma, Ba		umor Benign, o					1/50 (2%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Basal Cell Carcinoma									
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin:			nont or N	ne)					
Basal Cell Carcinoma or	Basosquamou	s Tumor (malig	(0%)) 3)			0/50 (0%)		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N Length of Study: CHRONIC

Toxicology Data Management System

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Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

			Male				Female	
#Skin: Basal Cell Carcinoma, I NOS), or Trichoepitheli		oma, Basosquamous Tu	mor (benign, maligna	nnt or				
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
≭Skin: Basal or Sq. Cell Carcir Adenoma, Papilloma, S	noma, Carcinoma oq Papilloma, Ker	a, Basosq. Tumor (M or atoacanthoma, Trichoe	B), Basal Cell Adeno pithelioma	ma,				
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%
#Skin: Fibroma Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
Skin: Fibroma, Fibrosarcoma overall Incidence	a, Sarcoma, Myx o	oma, Myxosarcoma, or I 3/50 (6%) 3/50 (6%)	Fibrous Histiocytoma Mean 6%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
Skin: Fibrosarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Fibrosarcoma, Sarcom						0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: RATS

Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 93

			Male				Female	
#Skin: Fibrous Histiocytoma		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Hemangiosarcoma		0/50 (00/)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Keratoacanthoma		0/50 (0%)				2/50 (4%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#Skin: Lipoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma		2/22 (221)				(20)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 94

			Male				Female	
#Skin: Neurofibroma or Schwan	•	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma or Sc	hwannoma (m	alignant or NOS)						
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma, Neur						0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Skin: Sarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
≄Skin: Schwannoma Benign		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Skin: Schwannoma Malignant								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

Page: 95

			Male				Female	
#Skin: Squamous Cell Carcinor	ma							
•		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin:		Carcinoma, Basosquamo						
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillom	na	0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Squamous Cell Papillom	na or Papilloma							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Skin: Squamous Cell Papillom	na, Papilloma, S	quamous Cell Carcinoma	or Keratoacanthon	na		3/50 (6%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%
#Skin: Squamous Cell Papillom	na, Papilloma, o	r Keratoacanthoma 0/50 (0%)				3/50 (6%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%
						` '		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 96

			Male				Female	
#Skin: Trichoepithelioma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma		0/50 (00()				0(50 (00))		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Spinal Cord: Glioma Malignant		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Stomach, Glandular: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 97

			Male				Female		
#Stomach, Glandular: Sarcoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Testes: Adenoma									
		45/50 (90%)							
Overall Incidence	Total	45/50 (90%)	Mean 90%	SD 0%					
*Testes: Hemangioma		0/50 (00)							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%					
		, ,							
*Thymus: Thymoma Benign		0/50 (00/)				0/40 (00/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	
*Thymus: Thymoma Malignant									
		0/50 (0%)				1/48 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/48 (2.08%)	Mean 2.08%	SD 0%	
*Thymus: Thymoma NOS		0/50 (00/)				0/49 /09/			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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Mean 0%

Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups Contract/Lab: All Laboratories

> Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Male Female *Thymus: Thymoma: Benign, Malignant, NOS 0/50 (0%)1/48 (2%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 1/48 (2.08%) Mean 2.08% SD 0% *Thyroid Gland: C-Cell: Adenoma 11/50 (22%)6/50 (12%) **Overall Incidence** Total 11/50 (22%) Mean 22% SD 0% Total 6/50 (12%) Mean 12% SD 0% *Thyroid Gland: C-Cell: Carcinoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Thyroid Gland: C-Cell: Carcinoma or Adenoma 11/50 (22%)6/50 (12%) **Overall Incidence** Total 11/50 (22%) Mean 22% SD 0% Total 6/50 (12%) Mean 12% SD 0% *Thyroid Gland: Follicular Cell: Adenoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Thyroid Gland: Follicular Cell: Carcinoma 1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total SD 0%

0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 99

			Male				Female	
*Thyroid Gland: Follicular C Carcinoma or Adenoma	Cell:							
		1/50 (2%	,			0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinom	na							
		0/50 (0%	,			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinom	-	0/50 (0%	,			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma				SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tongue:				SD 0% SD 0%	Total Total		Mean 0% Mean 0%	SD 0% SD 0%
#Tongue: Squamous Cell Papilloma	a Total	0/50 (0% 0/50 (0%)	%) Mean 0%			0/50 (0%) 0/50 (0%)		
#Tongue: Squamous Cell Papilloma Overall Incidence #Tooth: Adamantinoma Malignan	Total	0/50 (0% 0/50 (0%) 0/50 (0%	%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma Overall Incidence #Tooth:	a Total	0/50 (0% 0/50 (0%)	%) Mean 0%			0/50 (0%) 0/50 (0%)		
#Tongue: Squamous Cell Papilloma Overall Incidence #Tooth: Adamantinoma Malignan	Total	0/50 (0% 0/50 (0%) 0/50 (0%	%) Mean 0% %) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 100

			Male			Female			
*Urinary Bladder: Carcinoma or Papilloma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Urinary Bladder: Hemangiosarcoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Urinary Bladder: Papilloma						(201)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Adenoma						0/50 (09/)			
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Carcinoma	•••••								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Leiomyosarcoma						0/50 (00)			
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: WATER

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Page: 101

	Male			Female	
#Uterus: Polyp Stromal					
Overall Incidence		Total	8/50 (16%) 8/50 (16%)	Mean 16%	SD 0%
#Uterus: Sarcoma			•••••		
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma Stromal					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal					
Overall Incidence		Total	8/50 (16%) 8/50 (16%)	Mean 16%	SD 0%
#Uterus: Schwannoma Malignant					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Vagina: Polyp					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 102

			Male				Female	
#Vagina: Sarcoma						2(72)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Vagina: Schwannoma Malignant								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Adenoma		0/50 (00/)				0/50 (09/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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Report Date: 06/05/2013

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical	
					Male			
Battelle Northwest	052001105	07/14/03	729	50(5)	23(678)	526.9	1-Bromopropane	
Battelle Northwest	059901705	08/25/03	729	50(5)	28(686)	525.6	Diethylamine	
Battelle Northwest	059302507	06/16/03	729	50(5)	20(668)	536.2	Tetralin	
Battelle Northwest	052030305	06/06/05	729	50(5)	25(680)	532.1	Vinylidene chloride	
					Female			
Battelle Northwest	052001105	07/14/03	730	50(5)	34(702)	386.5	1-Bromopropane	
Battelle Northwest	059901705	08/25/03	730	50(5)	31(687)	378.3	Diethylamine	
Battelle Northwest	059302507	06/16/03	730	50(5)	31(682)	370.8	Tetralin	
Battelle Northwest	052030305	06/06/05	731	50(5)	30(705)	375.6	Vinylidene chloride	

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
All Organs: Benign Tumors								
		48/50 (96%) 47/50 (94%)	44/50 (88%)	48/50 (96%)		45/50 (90%) 47/50 (94%)	43/50 (86%)	40/50 (80%)
Overall Incidence	Total	187/200 (93.5%)	Mean 93.5%	SD 3.79%	Total	175/200 (87.5%)	Mean 87.5%	SD 5.97%
#All Organs: Malignant Tumors								
		38/50 (76%) 27/50 (54%)	31/50 (62%)	33/50 (66%)		26/50 (52%) 24/50 (48%)	24/50 (48%)	25/50 (50%)
Overall Incidence	Total	129/200 (64.5%)	Mean 64.5%	SD 9.15%	Total	99/200 (49.5%)	Mean 49.5%	SD 1.91%
#All Organs: Malignant and Benign T								
		50/50 (100%) 50/50 (100%)	49/50 (98%)	50/50 (100%)		49/50 (98%) 49/50 (98%)	48/50 (96%)	46/50 (92%)
Overall Incidence	Total	199/200 (99.5%)	Mean 99.5%	SD 1%	Total	192/200 (96%)	Mean 96%	SD 2.83%
All Organs: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#All Organs: Hemangiosarcoma or l	Hemangioma							
		0/50 (0%) 0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
#All Organs: Histiocytic Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 2%
Overall Incidence	Total	29/50 (58%) 17/50 (34%) 96/200 (48%)	25/50 (50%) Mean 48%	25/50 (50%) SD 10.07%	Total	16/50 (32%) 10/50 (20%) 58/200 (29%)	15/50 (30%) Mean 29%	17/50 (34%) SD 6.22%
#All Organs:								
Malignant Lymphoma:	Histiocytic, Lym	phocytic, Mixed, NOS, or	Undifferentiated Cel	I Type				
Malignant Lymphoma:	Histiocytic, Lym	phocytic, Mixed, NOS, or 0/50 (0%) 0/50 (0%)	Undifferentiated Cel 0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
	Histiocytic, Lym Total	0/50 (0%)			Total	` '	0/50 (0%) Mean 0.5%	0/50 (0%) SD 1%
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/200 (0.5%)	Mean 0.5%	SD 1%
Overall Incidence #All Organs:	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%)	0/50 (0%)	Total	1/50 (2%)	(,	(,

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
#All Organs: Mesothelioma: Malignant								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#All Organs: Osteoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma								
		2/50 (4%) 1/50 (2%)	0/50 (0%)	3/50 (6%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	6/200 (3%)	Mean 3%	SD 2.58%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#All Organs: Osteosarcoma or Osteoma								
		2/50 (4%) 2/50 (4%)	0/50 (0%)	3/50 (6%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	7/200 (3.5%)	Mean 3.5%	SD 2.52%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Adrenal Cortex:								
		1/50 (2%) 4/49 (8%)	1/50 (2%)	0/50 (0%)		3/50 (6%) 2/50 (4%)	4/50 (8%)	8/50 (16%)
Overall Incidence	Total	6/199 (3.02%)	Mean 3.04%	SD 3.54%	Total	17/200 (8.5%)	Mean 8.5%	SD 5.26%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Adrenal Cortex: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) 0/49 1/50 (2%)**Overall Incidence** Total 0/199 (0%) Mean 0% SD 0% Total 1/200 (0.5%) Mean 0.5% SD 1% *Adrenal Medulla: Pheochromocytoma Benign 10/50 (20%)7/50 (14%)9/50 (18%)2/50 (4%)0/50 (0%)2/50 (4%)5/49 (10%)0/50 (0%)Mean 15.55% **Overall Incidence** Total 31/199 (15.58%) SD 4.35% Total 4/200 (2%) Mean 2% SD 2.31% *Adrenal Medulla: **Pheochromocytoma Complex** 1/50 (2%)2/50 0/50 1/50 (2%)0/50 0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 3/199 (1.51%) Mean 1.5% SD 1.91% Total 1/200 (0.5%) SD 1% Mean 0.5% *Adrenal Medulla: **Pheochromocytoma Malignant** 0/50 (0%)(2%)4/50 0/50 (0%)0/50 (0%)1/50 (2%)1/50 2/49 (4%)1/50 (2%)**Overall Incidence** Total 7/199 (3.52%) Mean 3.52% SD 3.42% Total 2/200 (1%) Mean 1% SD 1.15% *Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS 11/50 (22%)10/50 (20%)12/50 (24%)3/50 (6%)0/50 (0%)3/50 (6%)6/49 (12%)1/50 (2%)**Overall Incidence** Total 39/199 (19.6%) Mean 19.56% SD 5.14% Total 7/200 (3.5%) Mean 3.5%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Blood Vessel: Leiomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Bone: Chordoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
₽Bone: Osteoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Bone: Osteosarcoma								
		1/50 (2%) 1/50 (2%)	0/50 (0%)	3/50 (6%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/200 (2.5%)	Mean 2.5%	SD 2.52%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Bone: Osteosarcoma or Osteoma								
		1/50 (2%) 2/50 (4%)	0/50 (0%)	3/50 (6%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	6/200 (3%)	Mean 3%	SD 2.58%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Brain: Glioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain: Glioma Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain: Glioma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Brain: Oligodendroglioma, Gli	oma, or Astrocy	rtoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Brain: Osteosarcoma							•••••	
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
Clitoral/Preputial Gland: Adenoma								
		4/50 (8%) 2/50 (4%)	0/50 (0%)	0/50 (0%)		3/49 (6%) 4/47 (9%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	6/200 (3%)	Mean 3%	SD 3.83%	Total	8/196 (4.08%)	Mean 4.16%	SD 3.86%
Clitoral/Preputial Gland: Carcinoma								
		2/50 (4%) 2/50 (4%)	1/50 (2%)	0/50 (0%)		1/49 (2%) 1/47 (2%)	0/50 (0%)	4/50 (8%)
Overall Incidence	Total	5/200 (2.5%)	Mean 2.5%	SD 1.91%	Total	6/196 (3.06%)	Mean 3.04%	SD 3.45%
Clitoral/Preputial Gland: Carcinoma or Adenoma								
		6/50 (12%) 4/50 (8%)	1/50 (2%)	0/50 (0%)		4/49 (8%) 5/47 (11%)	1/50 (2%)	4/50 (8%)
Overall Incidence	Total	11/200 (5.5%)	Mean 5.5%	SD 5.51%	Total	14/196 (7.14%)	Mean 7.2%	SD 3.67%
Clitoral/Preputial Gland: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/47 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/196 (0%)	Mean 0%	SD 0%
Ear: Neural Crest Tumor								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Eye: Melanoma Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Eye: Melanoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Harderian Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

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Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
*Heart: Schwannoma Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectu Adenoma	ım:							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectu Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Leiomyoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

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Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Male **Female** #Intestine Small: Duodenum: Schwannoma Malignant 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% #Intestine Small: Ileum: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% Overall Incidence Total 0/200 (0%) SD 0% Total 0/200 (0%) Mean 0% SD 0% #Intestine Small: Jejunum: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% #Intestine Small: Jejunum: Leiomyoma 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% #Intestine Small: Jejunum: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
fIntestine Small: Site Un	specified:							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Un Carcinoma	specified:							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Un Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	(070)	0,00 (0,0)		0/50 (0%)	0,00 (0,70)	0,00 (0,70)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Small: Site Una Leiomyoma	specified:							
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Un Leiomyosarcoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

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Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
#Intestine Small: Site Unspec Schwannoma Malignant	cified:							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma								
		0/50 (0%) 2/50 (4%)	6/50 (12%)	3/50 (6%)		0/50 (0%) 0/50 (0%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	11/200 (5.5%)	Mean 5.5%	SD 5%	Total	2/200 (1%)	Mean 1%	SD 2%
*Islets, Pancreatic: Carcinoma								
		3/50 (6%) 2/50 (4%)	1/50 (2%)	1/50 (2%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	7/200 (3.5%)	Mean 3.5%	SD 1.91%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Islets, Pancreatic: Carcinoma or Adenoma								
		3/50 (6%) 4/50 (8%)	7/50 (14%)	4/50 (8%)		1/50 (2%) 0/50 (0%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	18/200 (9%)	Mean 9%	SD 3.46%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%
*Kidney: Pelvis and Transition Papilloma		um:						
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/199 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Kidney: Renal Tubule: Adenoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/199 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/49 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%
*Kidney: Renal Tubule: Carcinoma or Adenoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/49 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%
'Kidney: Renal Tubule: Lipoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Mesenchymal Tumor Malig								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/199 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Kidney: Renal Tubule: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma	a							
		0/50 (0%) 1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	2/200 (1%)	Mean 1%	SD 1.15%
*Liver: Hepatocellular Carcinor								
		2/50 (4%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Liver: Hepatocellular Carcinor	na or Hepatobla	stoma						
		2/50 (4%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Liver: Hepatocellular Carcinor	na or Hepatocel	lular Adenoma						
-	•	2/50 (4%) 1/50 (2%)	0/50 (0%)	1/50 (2%)		1/50 (2%) 1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 1.63%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Male **Female** *Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma 2/50 (4%)0/50 (0%)1/50 (2%)1/50 (2%)1/50 (2%)0/50 (0%)1/50 (2%)1/50 (2%)3/200 (1.5%) **Overall Incidence** Total 4/200 (2%) Mean 2% SD 1.63% Total Mean 1.5% SD 1% *Liver: Ito Cell Tumor Benign (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% Overall Incidence Total 0/200 (0%) SD 0% Total 0/200 (0%) Mean 0% SD 0% *Lung: Alveolar/Bronchiolar Adenoma 2/50 (4%)0/50 0/50 (0%)1/50 (2%)0/50 0/50 (0%)3/50 (6%)1/50 (2%)**Overall Incidence** Total 5/200 (2.5%) Mean 2.5% SD 3% Total 2/200 (1%) Mean 1% SD 1.15% *Lung: Alveolar/Bronchiolar Carcinoma 1/50 (2%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 3/200 (1.5%) Mean 1.5% SD 1% Total 1/200 (0.5%) Mean 0.5% SD 1% *Lung: Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma 3/50 (6%)1/50 (2%)1/50 (2%)2/50 (4%)0/50 (0%)0/50 (0%)3/50 (6%)1/50 (2%)**Overall Incidence** Total 8/200 (4%) Mean 4% SD 2.31% Total 3/200 (1.5%) Mean 1.5%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
*Lung: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenolipoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Mammary Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		4/50 (8%) 5/50 (10%)	9/50 (18%)	3/50 (6%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	21/200 (10.5%)	Mean 10.5%	SD 5.26%
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		4/50 (8%) 5/50 (10%)	10/50 (20%)	3/50 (6%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	22/200 (11%)	Mean 11%	SD 6.22%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Mammary Gland: Fibroadenoma								
		2/50 (4%) 1/50 (2%)	2/50 (4%)	1/50 (2%)		25/50 (50%) 37/50 (74%)	27/50 (54%)	14/50 (28%)
Overall Incidence	Total	6/200 (3%)	Mean 3%	SD 1.15%	Total	103/200 (51.5%)	Mean 51.5%	SD 18.86%
#Mammary Gland: Fibroma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma	or Adenoma	2/50 (4%)	2/50 (4%)	1/50 (2%)		25/50 (50%)	27/50 (54%)	14/50 (28%)
		2/50 (4%) 1/50 (2%)	2/50 (4%)	1/50 (2%)		25/50 (50%) 37/50 (74%)	27/50 (54%)	14/50 (28%)
Overall Incidence	Total	6/200 (3%)	Mean 3%	SD 1.15%	Total	103/200 (51.5%)	Mean 51.5%	SD 18.86%
#Mammary Gland: Fibroma, Fibroadenoma								
		2/50 (4%) 1/50 (2%)	2/50 (4%)	1/50 (2%)		27/50 (54%) 38/50 (76%)	30/50 (60%)	16/50 (32%)
Overall Incidence	Total	6/200 (3%)	Mean 3%	SD 1.15%	Total	111/200 (55.5%)	Mean 55.5%	SD 18.21%
#Mesentery: Fibrous Histiocytoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
#Mesentery: Schwannoma Malignar	nt							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Nose: Adenoma								
		0/50 (0%) 0/49 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Oral Cavity (Oral Mucos	a, Tongue, Phar		•••••					•••••
Squamous Cell Carcino	oma	1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	2/200 (1%)	Mean 1%	SD 1.15%
#Oral Cavity (Oral Mucos	a, Tongue, Phar	ynx, Tooth, Gingiva): Squamous, or Papilloma		0/50 (00%)		0/50 (00)	0/50 (00/)	4/50 (00)
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	2/200 (1%)	Mean 1%	SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male					Female	
#Oral Mucosa: Squamous Cell Carcinoma	1								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 ((0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%		Total	0/200 (0%)	Mean 0%	SD 0%
#Oral Mucosa: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)	0/50 ((0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/30 (0/8)	0/30 ((0 %)		0/50 (0%)	0/30 (0 /8)	0/30 (0 /8)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%		Total	0/200 (0%)	Mean 0%	SD 0%
*Ovary: Cystadenoma									
							0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence						Total	0/200 (0%)	Mean 0%	SD 0%
*Ovary: Fibrosarcoma						•••••			
							0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence						Total	0/200 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor Ben	ign								
							0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence						Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

	Male		Female	
*Ovary: Granulosa Cell Tumor Malignant				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa-Theca Tumor Malignant				
		2/50 (4%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%
*Ovary: Schwannoma Malignant				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%
*Ovary: Sertoli Cell Tumor Malignant				
_		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Ovary: **Tubulostromal Adenoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% *Pancreas: Adenoma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% Mean 0% Overall Incidence Total 0/199 (0%) SD 0% Total 0/200 (0%) SD 0% *Pancreas: Carcinoma or Adenoma 0/50 (0%)0/49 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/199 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% *Pancreas: **Mixed Tumor Benign** 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/199 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% *Parathyroid Gland: Adenoma 0/46 (0%)0/48 (0%)0/48 (0%)0/47 (0%)1/43 (2%)(0%)0/49 0/50 (0%)(0%)**Overall Incidence** Total 0/192 (0%) Mean 0% SD 0% Total 1/188 (0.53%) Mean 0.58% SD 1.16%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups Route: INHALATION

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Report Date: 06/05/2013

Vehicle: AIR

			Male				Female	
Pituitary Gland: Pars Di Adenoma	stalis or Unspec	ified Site:						
		37/50 (74%) 34/50 (68%)	31/50 (62%)	36/50 (72%)		35/50 (70%) 32/50 (64%)	29/50 (58%)	36/49 (73%)
Overall Incidence	Total	138/200 (69%)	Mean 69%	SD 5.29%	Total	132/199 (66.33%)	Mean 66.37%	SD 6.81%
*Pituitary Gland: Pars Di Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 1/50 (2%)	2/50 (4%)	0/49 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	3/199 (1.51%)	Mean 1.5%	SD 1.91%
*Pituitary Gland: Pars Di Carcinoma or Adenom Overall Incidence		37/50 (74%) 34/50 (68%) 139/200 (69.5%)	31/50 (62%) Mean 69.5%	37/50 (74%) SD 5.74%	Total	35/50 (70%) 33/50 (66%) 135/199 (67.84%)	31/50 (62%) Mean 67.87%	36/49 (73%) SD 4.96%
Pituitary Gland: Pars Di Ganglioneuroma	stalis or Unspec	ified Site:			•••••			
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/199 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars In	termedia:							
*Pituitary Gland: Pars In Adenoma	termedia:	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%) 0/199 (0%)	0/50 (0%)	0/49 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male			Female	
*Pituitary Gland: Pars Interi Carcinoma or Adenoma	media:						
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/199 (0%) Mean 0% SD 0%	
*Pituitary Gland: Pars Nerve							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/199 (0%) Mean 0% SD 0%	
*Prostate: Adenoma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%			
*Prostate: Carcinoma or Adenoma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%			
*Salivary Glands: Carcinoma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%) Mean 0% SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Salivary Glands: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Salivary Glands: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Salivary Glands: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Fibrous Histiocytoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
Skeletal Muscle: Lipoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Basal Cell Adenoma or E	Basosquamous Total	5 Tumor Benign 0/50 (0%) 1/50 (2%) 2/200 (1%)	0/50 (0%) Mean 1%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 1/50 (2%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	0/50 (0%) SD 1%
Skin: Basal Cell Adenoma, Ba	sosquamous T	umor Benign, or Trichoe	pithelioma					
		0/50 (0%) 2/50 (4%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Basal Cell Carcinoma								
		0/50 (0%) 1/50 (2%)	1/50 (2%)	3/50 (6%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/200 (2.5%)	Mean 2.5%	SD 2.52%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS Strain: F 344/N **Toxicology Data Management System**

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Report Date: 06/05/2013

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Male **Female** #Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) (0%)1/50 (2%)3/50 (6%)0/50 (0%)0/50 (0%)0/50 (0%)(2%)(0%) 1/50 0/50 0/200 (0%) Mean 0% Overall Incidence Total 5/200 (2.5%) Mean 2.5% SD 2.52% Total SD 0% #Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 0/50 (0%)1/50 (2%)4/50 (8%)0/50 (0%)0/50 (0%)0/50 (0%)3/50 (6%) 1/50 (2%)8/200 (4%) SD 3.65% Overall Incidence Total Mean 4% Total 1/200 (0.5%) Mean 0.5% SD 1% #Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosg. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma 1/50 (2%)1/50 5/50 (10%)1/50 (2%)1/50 1/50 (2%)9/50 (18%)2/50 (4%)**Overall Incidence** Total 16/200 (8%) Mean 8% SD 7.66% 5/200 (2.5%) SD 1% Total Mean 2.5% #Skin: **Fibroma** 3/50 (6%)1/50 (2%)3/50 (6%)2/50 (4%)1/50 (2%)0/50 (0%)(2%)1/50 (2%)1/50 **Overall Incidence** Total 8/200 (4%) Mean 4% SD 2.31% Total 4/200 (2%) Mean 2% SD 1.63% #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma (6%)2/50 (4%)6/50 (12%)2/50 (4%)1/50 (2%)0/50 (0%)(2%)(2%)1/50 1/50 **Overall Incidence** 12/200 (6%) SD 4.32% SD 1.63% Total Mean 6% Total 4/200 (2%) Mean 2%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
#Skin: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	3/50 (6%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 3%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Fibrosarcoma, Sarcoma, I								
	•	0/50 (0%) 0/50 (0%)	1/50 (2%)	3/50 (6%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 2.83%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Fibrous Histiocytoma			•••••					
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Keratoacanthoma								
		0/50 (0%) 3/50 (6%)	0/50 (0%)	1/50 (2%)		1/50 (2%) 1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 2.83%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Lipoma								
		2/50 (4%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Neurofibroma or Schwa	annoma benign							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma or	Schwannoma (m	alignant or NOS)						
	`	0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
Skin: Neurofibrosarcoma, Neurofi	broma, or s	Schwannoma (benign, ma	alignant or NOS)					
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
∜Skin: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Schwannoma Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date: 06/05/2013

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			Male				Female	
#Skin: Squamous Cell Carcino or Carcinoma	oma, Basal Cell	Carcinoma, Basosquamo	us Tumor (malignant	or NOS),				
		1/50 (2%) 1/50 (2%)	1/50 (2%)	3/50 (6%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	6/200 (3%)	Mean 3%	SD 2%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Squamous Cell Papillo	oma	0/50 (00/)	0/50 (00)	0/50 (00)		0/50 (004)	0/50 (004)	0/50 (00/)
		0/50 (0%) 3/50 (6%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 3%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillo	oma or Papilloma	ı 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		3/50 (6%)	,	,		0/50 (0%)	0,00 (0,0)	,
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 3%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillo	oma, Papilloma, S	Squamous Cell Carcinom 1/50 (2%)	a or Keratoacanthoma	a 1/50 (2%)		1/50 (2%)	1/50 (2%)	1/50 (2%)
		6/50 (12%)	0/00 (0/0)	1700 (270)		1/50 (2%)	1700 (270)	1700 (270)
Overall Incidence	Total	8/200 (4%)	Mean 4%	SD 5.42%	Total	4/200 (2%)	Mean 2%	SD 0%
#Skin: Squamous Cell Papillo	oma, Papilloma, c	or Keratoacanthoma						
		0/50 (0%) 6/50 (12%)	0/50 (0%)	1/50 (2%)		1/50 (2%) 1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	7/200 (3.5%)	Mean 3.5%	SD 5.74%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Sele

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Trichoepithelioma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	0/200 (0%)	Mean 0%	SD 0%
#Spinal Cord: Glioma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male		Female	
#Stomach, Glandular: Carcinoma or Adenoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total 0/200 (0%) Mean 0% SD 0%	
#Stomach, Glandular: Sarcoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total 0/200 (0%) Mean 0% SD 0%	
*Testes: Adenoma						
		34/50 (68%) 32/50 (64%)	36/50 (72%)	29/50 (58%)		
Overall Incidence	Total	131/200 (65.5%)	Mean 65.5%	SD 5.97%		
*Testes: Hemangioma						
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%		
*Thymus: Thymoma Benign						
		0/43 (0%) 0/42 (0%)	0/44 (0%)	0/47 (0%)	1/46 (2%) 0/48 (0%) 0/44 (0%) 0/46 (0%)	
Overall Incidence	Total	0/176 (0%)	Mean 0%	SD 0%	Total 1/184 (0.54%) Mean 0.54% SD 1.09%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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Report Date: 06/05/2013

			Male				Female	
Thymus: Thymoma Malignant								
		0/43 (0%) 0/42 (0%)	0/44 (0%)	0/47 (0%)		0/46 (0%) 0/46 (0%)	0/48 (0%)	0/44 (0%)
Overall Incidence	Total	0/176 (0%)	Mean 0%	SD 0%	Total	0/184 (0%)	Mean 0%	SD 0%
Thymus: Thymoma NOS								
		0/43 (0%) 0/42 (0%)	0/44 (0%)	0/47 (0%)		0/46 (0%) 0/46 (0%)	1/48 (2%)	0/44 (0%)
Overall Incidence	Total	0/176 (0%)	Mean 0%	SD 0%	Total	1/184 (0.54%)	Mean 0.52%	SD 1.04%
Thymus: Thymoma: Benign, Maliç						•••••		
		0/43 (0%) 0/42 (0%)	0/44 (0%)	0/47 (0%)		1/46 (2%) 0/46 (0%)	1/48 (2%)	0/44 (0%)
Overall Incidence	Total	0/176 (0%)	Mean 0%	SD 0%	Total	2/184 (1.09%)	Mean 1.06%	SD 1.23%
Thyroid Gland: C-Cell: Adenoma								
		5/50 (10%) 4/50 (8%)	7/50 (14%)	5/50 (10%)		3/50 (6%) 3/50 (6%)	4/50 (8%)	3/50 (6%)
Overall Incidence	Total	21/200 (10.5%)	Mean 10.5%	SD 2.52%	Total	13/200 (6.5%)	Mean 6.5%	SD 1%

2/50

SD 2.58%

(4%)

1/50

0/50

Total

1/200 (0.5%)

(2%)

(0%)

0/50

(0%)

Mean 0.5%

0/50

SD 1%

(0%)

Total

4/50

3/50

10/200 (5%)

(8%)

(6%)

1/50

Mean 5%

(2%)

Carcinoma

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male			Female	
*Thyroid Gland: C-Cell: Carcinoma or Adenoma							
		9/50 (18%) 7/50 (14%)	8/50 (16%) 6/5	50 (12%)		4/50 (8%) 4/50 (8%) 3/50 (6%)	3/50 (6%)
Overall Incidence	Total	30/200 (15%)		2.58%	Total	14/200 (7%) Mean 7%	SD 1.15%
*Thyroid Gland: Follicular Cel Adenoma							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/5	50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD	0%	Total	0/200 (0%) Mean 0%	SD 0%
*Thyroid Gland: Follicular Cel Carcinoma	l:						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/5	50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)		0%	Total	0/200 (0%) Mean 0%	SD 0%
*Thyroid Gland: Follicular Cel Carcinoma or Adenoma							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/5	50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD	0%	Total	0/200 (0%) Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/5	50 (0%)		0/50 (0%) 0/50 (0%) 1/50 (2%)	1/50 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD	0%	Total	2/200 (1%) Mean 1%	SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Male **Female** #Tongue: Squamous Cell Carcinoma or Papilloma Squamous 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 2/200 (1%) Mean 1% SD 1.15% #Tongue: **Squamous Cell Papilloma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% Mean 0% **Overall Incidence** Total 0/200 (0%) SD 0% Total 0/200 (0%) SD 0% #Tooth: **Adamantinoma Malignant** 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/200 (0%) Mean 0% SD 0% *Urinary Bladder: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/199 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% *Urinary Bladder: Carcinoma or Papilloma 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 1/199 (0.5%) Mean 0.5% SD 1% Total 0/200 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Urinary Bladder: Hemangiosarcoma 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 1/199 (0.5%) Mean 0.5% SD 1% Total 0/200 (0%) Mean 0% SD 0% *Urinary Bladder: **Papilloma** 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 1/199 (0.5%) Mean 0.5% SD 1% Total 0/200 (0%) SD 0% #Uterus: Adenoma 0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 2/200 (1%) Mean 1% SD 1.15% #Uterus: Carcinoma 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% #Uterus: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

#Uterus:

#Uterus: Sarcoma

#Uterus:

#Uterus:

#Uterus:

Overall Incidence

Toxicology Data Management System

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Report Date: 06/05/2013

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Male **Female Polyp Stromal** 8/50 (16%)8/50 (16%) (12%)11/50 (22%)**Overall Incidence** Total 33/200 (16.5%) Mean 16.5% SD 4.12% 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/200 (0%) SD 0% Sarcoma Stromal 2/50 (4%)0/50 0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/200 (1%) Mean 1% SD 2% Sarcoma Stromal or Polyp Stromal 10/50 (20%)8/50 (16%) 6/50 (12%) 11/50 (22%)**Overall Incidence** Total 35/200 (17.5%) Mean 17.5% SD 4.43% Schwannoma Malignant

0/50

0/50

0/200 (0%)

Total

(0%)

(0%)

0/50

(0%)

Mean 0%

0/50

SD 0%

(0%)

.....

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Vagina: Polyp								
						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%
#Vagina:								
Sarcoma						1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Vagina: Schwannoma Malignant								
-						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	0/200 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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		Male				Female			
#Zymbal's Gland: Carcinoma or Adenoma									
		0/50 (0%) 0/50 (0%)	2/50 (4%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	2/200 (1%)	Mean 1%	SD 1.15%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 143

Report Date: 06/05/2013

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory	052000903	11/18/04	726	50(3)	33(668)	516.1	beta-Picoline
					Female		
Battelle Columbus Laboratory	052000903	11/19/04	727	50(5)	30(688)	352.7	beta-Picoline

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Male **Female** #All Organs: **Benign Tumors** 45/50 (90%)47/50 (94%)**Overall Incidence** Total 45/50 (90%) Mean 90% SD 0% Total 47/50 (94%) Mean 94% SD 0% #All Organs: **Malignant Tumors** 23/50 (46%)17/50 (34%)**Overall Incidence** Total 23/50 (46%) Mean 46% SD 0% Total 17/50 (34%) Mean 34% SD 0% #All Organs: **Malignant and Benign Tumors** 48/50 (96%)49/50 (98%)**Overall Incidence** Total 48/50 (96%) Mean 96% SD 0% Total 49/50 (98%) Mean 98% SD 0% #All Organs: Hemangioma 0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% **#All Organs:** Hemangiosarcoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% **#All Organs:** Hemangiosarcoma or Hemangioma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

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Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Contract/Lab: All Laboratories

Strain: F 344/N Length of Study: CHRONIC

#All Organs:				Male			Female				
Mean 0	•										
#All Organs: Leukemia: Lymphocytic, Monocytic, Monocyti	•		0/50 (0%)				0/50 (0%)				
Leukemia: Lymphocytic, Monotuclear, or Undifferentiated 14/50 (28%) Mean 28% SD 0% Total 12/50 (24%) Mean 24% SD 0%	Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
14/50 (28%) Mean 28% SD 0% Total 12/50 (24%) Mean 24% SD 0%	#All Organs:										
Overall Incidence Total 14/50 (28%) Mean 28% SD 0% Total 12/50 (24%) Mean 24% SD 0% #All Organs: Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #All Organs: Mesothelioma: Malignant: Mesothelioma: Malignant: Mesothelioma: Malignant: Mesothelioma: Malignant: Mesothelioma: Malignant: Mesothelioma: Malignant: Mesothelioma: Mesotheli	Leukemia: Lymphocytic	c, Monocytic, Mo		ntiated			12/50 (24%)				
#All Organs: Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type			14/50 (28%)				12/50 (24%)		SD 0%		
Overall Incidence Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #All Organs:											
Overall Incidence Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #All Organs:	Malignant Lymphoma: I	Histiocytic, Lym		r Undifferentiated Ce	II Type		0/50 (00/)				
#All Organs:		-	, ,		05.00/	-	` '		00.007		
Mesothelioma: Benign, Malignant, NOS 4/50 (8%) Mean 8% SD 0% Total 0/50 (0%) Mean 0% SD 0% #All Organs: Mesothelioma: Malignant 4/50 (8%) Mean 8% SD 0% Total 0/50 (0%) Mean 0% SD 0% Overall Incidence Total 4/50 (8%) Mean 8% SD 0% Total 0/50 (0%) Mean 0% SD 0% #All Organs: Osteoma	Overali incidence	ıotaı	0/50 (0%)	iviean 0%	SD 0%	ı otal	0/50 (0%)	wean 0%	SD 0%		
Overall Incidence Total 4/50 (8%) Mean 8% SD 0% Total 0/50 (0%) Mean 0% SD 0% #All Organs: Mesothelioma: Malignant 4/50 (8%) Mean 8% SD 0% Total 0/50 (0%) Mean 0% SD 0% Overall Incidence Total 4/50 (8%) Mean 8% SD 0% Total 0/50 (0%) Mean 0% SD 0% #All Organs: Osteoma	•	Malian and NOO									
Overall Incidence Total 4/50 (8%) Mean 8% SD 0% Total 0/50 (0%) Mean 0% SD 0% 4/50 (8%) Mean 8% SD 0% Total 0/50 (0%) Mean 0% SD 0% Osteoma Osteoma A/50 (8%) Mean 8% SD 0% Total 0/50 (0%) Mean 0% SD 0%	Mesotnelloma: Benign,	Malignant, NOS					0/50 (0%)				
Mesothelioma: Malignant 4/50 (8%) 0/50 (0%) Overall Incidence Total 4/50 (8%) Mean 8% SD 0% Total 0/50 (0%) Mean 0% SD 0% #All Organs: Osteoma Osteoma Osteoma <td>Overall Incidence</td> <td>Total</td> <td>` '</td> <td>Mean 8%</td> <td>SD 0%</td> <td>Total</td> <td>` '</td> <td>Mean 0%</td> <td>SD 0%</td>	Overall Incidence	Total	` '	Mean 8%	SD 0%	Total	` '	Mean 0%	SD 0%		
4/50 (8%) Overall Incidence Total 4/50 (8%) Mean 8% SD 0% Total 0/50 (0%) #All Organs: Osteoma	#All Organs:										
Overall Incidence Total 4/50 (8%) Mean 8% SD 0% Total 0/50 (0%) Mean 0% SD 0% #All Organs: Osteoma	Mesothelioma: Maligna	nt									
#All Organs: Osteoma			4/50 (8%)				0/50 (0%)				
Osteoma	Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
0 (= 0											
			0/50 (0%)				0/50 (0%)				
Overall Incidence Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%	Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 146

			Male			Female			
#All Organs: Osteosarcoma		0/50 (0%)		SD 0%/		0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#All Organs: Osteosarcoma or Osteoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Adrenal Cortex: Adenoma		1/50 (2%)				2/50 (4%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
*Adrenal Cortex: Carcinoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Benign		5/50 (10%)				2/50 (4%)			
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Comple	ex	4/50 (00())				0/50 /00/			
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 147

			Male				Female				
*Adrenal Medulla: Pheochromocytoma Malignant											
•	-	0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Adrenal Medulla: Pheochromocytoma: B											
	og, oop.o,	6/50 (12%)				2/50 (4%)					
Overall Incidence	Total	6/50 (12%)	Mean 12%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%			
#Blood Vessel: Leiomyosarcoma	•••••	0/50 (00/)				0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Bone: Chordoma		, ,				, ,					
Overall Incidence	Tatal	0/50 (0%)	Mann 00/	CD 00/	Tatal	0/50 (0%)	Maan 00/	SD 0%			
Overali incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%				
#Bone: Osteoma											
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Bone: Osteosarcoma		2/20 (201)				(201)					
	-	0/50 (0%)		00.00/	-	0/50 (0%)	NA 00/	05 00/			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 148

			Male			Female			
#Bone: Osteosarcoma or Osteoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Brain: Glioma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Brain: Glioma Benign		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
		, ,				, ,			
*Brain: Glioma Malignant		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Brain: Oligodendroglioma, Glioma									
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
*Brain: Osteosarcoma									
Occupation of the second	Tatal	0/50 (0%)	Mara 00/	00.00/	Tatal	0/50 (0%)	Marana 00/	OD 00/	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 149

			Male			Female				
*Clitoral/Preputial Gland: Adenoma										
		0/50 (0%)				7/50 (14%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	7/50 (14%)	Mean 14%	SD 0%		
*Clitoral/Preputial Gland: Carcinoma										
		2/50 (4%)				0/50 (0%)				
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Clitoral/Preputial Gland: Carcinoma or Adenoma		2/50 / 40/				7/50 (4.40/)				
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	7/50 (14%) 7/50 (14%)	Mean 14%	SD 0%		
		, ,				, ,				
*Clitoral/Preputial Gland: Sarcoma		0/50 (00/)				(70 (70))				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
#Ear: Neural Crest Tumor										
		1/50 (2%)				0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Eye: Melanoma Benign		0.75								
Overell Incidence	Tatal	0/50 (0%)		CD 00/	Tatal	0/50 (0%)	Mana 00/	CD 00/		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Report Date: 06/05/2013

Page: 150

Species: RATS Strain: F 344/N

Vehicle: WATER

Length of Study: CHRONIC

			Male			Female			
#Eye: Melanoma Malignant		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Harderian Gland: Adenoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Harderian Gland: Carcinoma									
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Harderian Gland: Carcinoma or Adenoma		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Heart: Schwannoma Benign									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Heart: Schwannoma Malignant		0/50 (00)				0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 151

		·	Male				Female			
#Intestine Large: Colon/Recti Adenoma	um:									
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Large: Colon/Recti	um:			•••••						
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Duodenum: Leiomyoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Duodenum: Schwannoma Malignant						0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Ileum: Adenoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Jejunum: Carcinoma						0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female			
#Intestine Small: Jejunum: Leiomyoma		0/50 (00/)				0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Jejunum: Leiomyosarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Site Unspec Adenoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Site Unspec Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Site Unspec Carcinoma or Adenoma	cified:								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Site Unspec Leiomyoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

Page: 153

			Male	•		Female			
#Intestine Small: Site Unspe Leiomyosarcoma	ecified:								
Overall Incidence	Total	0/50 (09 0/50 (0%)	%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Site Unspe Schwannoma Malignant	ecified:					•••••			
Overall Incidence	Total	0/50 (09 0/50 (0%)	%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Islets, Pancreatic: Adenoma		4/50 (8 ^s	27.)			0/50 (0%)			
Overall Incidence	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Islets, Pancreatic: Carcinoma		0/50 /05				0/50 (00/)			
Overall Incidence	Total	0/50 (09 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Islets, Pancreatic: Carcinoma or Adenoma	•••••								
Overall Incidence	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Kidney: Pelvis and Transiti Papilloma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	%) Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Vehicle: WATER

Page: 154

			Male			Female				
*Kidney: Renal Tubule: Adenoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%		
*Kidney: Renal Tubule: Carcinoma		0/50 (00/)								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%		
*Kidney: Renal Tubule: Carcinoma or Adenoma		0/50 (0%)				0/49 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%		
*Kidney: Renal Tubule: Lipoma		0/50 (0%)		OD 00/	-	0/49 (0%)		00.00		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%		
*Kidney: Renal Tubule: Mesenchymal Tumor Malig	gnant	0/50 (00/)				0/40 (00/)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%		
*Kidney: Renal Tubule: Sarcoma						0/40 (09/)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 155

				Male			Female				
*Liver: Hepatocellular Adenoma 3/50 (6%) 2/50 (4%)											
Overall Incidence	Total	3/50 3/50 (6%)	(6%)	Mean 6%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%		
*Liver: Hepatocellular Carcinom	na										
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Liver: Hepatocellular Carcinom	na or Hepatobla		(00/)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Liver: Hepatocellular Carcinom		lular Adenoma 3/50	(6%)				2/50 (4%)				
Overall Incidence	Total	3/50 (6%)		Mean 6%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%		
*Liver: Hepatocellular Carcinom		ar Adenoma, or					2/50 (4%)				
Overall Incidence	Total	3/50 (6%)	(-,-)	Mean 6%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%		
*Liver: Ito Cell Tumor Benign		0/50	(00()				0/50 (00)				
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

SD 0%

Mean 0%

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Lung: Alveolar/Bronchiolar Adenoma 3/50 (6%)0/50 (0%)**Overall Incidence** Total 3/50 (6%) Mean 6% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Lung: Alveolar/Bronchiolar Carcinoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Lung: Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma 3/50 (6%)0/50 (0%)**Overall Incidence** Total 3/50 (6%) Mean 6% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Lung: **Fibrosarcoma** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total Mean 0% SD 0% 0/50 (0%) #Mammary Gland: Adenolipoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Mammary Gland: Adenoma 0/50 (0%)0/50 (0%)

SD 0%

Total

0/50 (0%)

Total

0/50 (0%)

Mean 0%

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 157

			Male			Female			
		(0%)				2/50 (4%)			
Total	0/50 (0%)		Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
		(0%)				2/50 (4%)			
	0/50 (0%)		Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
		(001)							
Tatal		(2%)	Mana 20/	CD 00/	Tatal	, ,	Mann C00/	CD 00/	
	, ,				1 Otal	34/50 (68%)	wean 68%	SD 0%	
	0/50	(00/.)				0/50 (00/)			
Total	0/50 (0%)	,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
	1/50	(2%)				34/50 (68%)			
Total	1/50 (2%)		Mean 2%	SD 0%	Total	34/50 (68%)	Mean 68%	SD 0%	
Carcinoma, or		(00/)				24/50 (000)			
Total		(2%)	Moon 29/	SD 0%	Total	` ,	Moon 68%	SD 0%	
	Total or Adenoma Total	Total 0/50 (0%) 0/50 Total 0/50 (0%) 1/50 Total 1/50 (2%) Total 0/50 (0%) Or Adenoma 1/50 Total 1/50 (2%) Carcinoma, or Adenoma 1/50	Total 0/50 (0%) 0/50 (0%) Total 0/50 (0%) 1/50 (2%) Total 1/50 (2%) Total 0/50 (0%) Total 0/50 (0%) or Adenoma 1/50 (2%) Total 1/50 (2%) Carcinoma, or Adenoma 1/50 (2%)	0/50 (0%) Total 0/50 (0%) Mean 0% 0/50 (0%) Total 0/50 (0%) Mean 0% 1/50 (2%) Total 1/50 (2%) Mean 2% 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% or Adenoma 1/50 (2%) Total 1/50 (2%) Mean 2% Carcinoma, or Adenoma 1/50 (2%)	0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% 1/50 (2%) Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0% SD 0% Or Adenoma 1/50 (2%) Mean 2% SD 0%	Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 1/50 (2%) Mean 2% SD 0% Total 1/50 (0%) Mean 0% SD 0% Total 1/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total or Adenoma 1/50 (2%) Mean 2% SD 0% Total Carcinoma, or Adenoma 1/50 (2%)	Total 0/50 (0%) Mean 0% SD 0% Total 2/50 (4%) Total 0/50 (0%) Mean 0% SD 0% Total 2/50 (4%) Total 0/50 (0%) Mean 0% SD 0% Total 2/50 (4%) Total 1/50 (2%) Mean 2% SD 0% Total 34/50 (68%) Total 0/50 (0%) Mean 0% SD 0% Total 34/50 (68%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 1/50 (2%) Mean 0% SD 0% Total 0/50 (68%) Carcinoma, or Adenoma 1/50 (2%) Mean 2% SD 0% Total 34/50 (68%)	Total 0/50 (0%) Mean 0% SD 0% Total 2/50 (4%) Mean 4% 0/50 (0%)	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 158

			Male			Female			
#Mesentery: Fibrous Histiocytoma									
	+	0/50 (0%)		OD 00/		0/50 (0%)		05.00/	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Mesentery: Schwannoma Malignar	nt								
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Nose: Adenoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Oral Cavity (Oral Mucos Papilloma Squamous o Overall Incidence	sa, Tongue, Phary or Papilloma Total	vnx, Tooth, Gingiva): 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Oral Cavity (Oral Mucos Squamous Cell Carcine				•••••		•••••			
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Oral Cavity (Oral Mucos	a, Tongue, Phary					0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male				Female	
#Oral Mucosa: Squamous Cell Carcino	ma							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		0/30 (0/8)						
#Oral Mucosa: Squamous Cell Papillon	na	0/50 (00/)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Cystadenoma						0/50 (00)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Fibrosarcoma						0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor B								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor N	<i>l</i> lalignant					(201)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male				Female			
*Ovary: Granulosa Cell Tumor: B	enign, Malign	ant, NOS				0.750 (001)				
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Ovary: Granulosa-Theca Tumor	Malignant					0/50 (0%)				
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%		
*Ovary: Schwannoma Malignant										
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
*Ovary: Sertoli Cell Tumor Maligi										
Overall Incidence					Total	, ,	Mean 0%	SD 0%		
*Ovary: Tubulostromal Adenoma	ı									
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Pancreas: Adenoma						(00)				
Overall Incidence	Total	1/49 (2%) 1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

			Male				Female		
*Pancreas: Carcinoma or Adenoma	1								
		1/49 (2%)				0/50 (0%)			
Overall Incidence	Total	1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Pancreas: Mixed Tumor Benign									
		0/49 (0%)				0/50 (0%)			
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Parathyroid Gland: Adenoma		2/-2 (22)				-/			
		0/50 (0%)				0/47 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%	
*Pituitary Gland: Pars Dis Adenoma	talis or Unspeci	ified Site:							
		28/50 (56%)				30/50 (60%)			
Overall Incidence	Total	28/50 (56%)	Mean 56%	SD 0%	Total	30/50 (60%)	Mean 60%	SD 0%	
*Pituitary Gland: Pars Dis									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Pituitary Gland: Pars Dis Carcinoma or Adenoma	talis or Unspeci								
	=	28/50 (56%)				30/50 (60%)			
Overall Incidence	Total	28/50 (56%)	Mean 56%	SD 0%	Total	30/50 (60%)	Mean 60%	SD 0%	
		(/				(/			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Vehicle: WATER

Page: 162

				Male			Female					
*Pituitary Gland: Pars Distalis or Unspecified Site: Ganglioneuroma												
Overall Incidence	Total	0/50 (0 0/50 (0%)	%) Mean	0% SD 0%	6 Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
*Pituitary Gland: Pars Intern	media:											
Overall Incidence	Total	0/50 (0 0/50 (0%)	%) Mean	0% SD 0%	6 Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
*Pituitary Gland: Pars Interr Carcinoma or Adenoma	nedia:	0/50 (0	%)			0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean	0% SD 0%	6 Total	0/50 (0%)	Mean 0%	SD 0%				
*Pituitary Gland: Pars Nervo Craniopharyngioma						0/50 (00/)						
Overall Incidence	Total	0/50 (0%)	%) Mean			0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
*Prostate: Adenoma												
Overall Incidence	Total	0/49 (0%)	%) Mean	0% SD 0%	6							
*Prostate: Carcinoma or Adenoma			%)									
Overall Incidence	Total	0/49 (0%)	Mean									

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 163

			Male				Female	
*Salivary Glands: Carcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: Sarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: Schwannoma Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Fibrous Histiocytoma		0/50 (00()				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 164

				Male				Female	
#Skeletal Muscle: Lipoma									
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma									
		1/50	(2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Basal Cell Adenoma or E	3asosquamous	Tumor Benign 1/50	(2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Basal Cell Adenoma, Ba		umor Benign, o					1/50 (2%)		
Overall Incidence	Total	1/50 (2%)	,	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Basal Cell Carcinoma									
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma or	Basosquamou		nant or NO	OS)			0/50 (0%)		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 165 Report Date: 06/05/2013

Species: RATS Strain: F 344/N Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

#Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 1/50 (2%) 1/50 (2%)													
/50 (2%)				1/50 (2%)									
` '		SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%							
. Tumor (M or B), Ba	sal Cell Adenoma,												
	Oma			1/50 (2%)									
` '	Mean 12%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%							
/50 (6%)				2/50 (4%)									
(6%) I		SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%							
osarcoma, or Fibrous				2/50 (4%)									
(8%)	Mean 8%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%							
/50 (2%)				0/50 (0%)									
(2%)		SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%							
us Histiocytoma				0/50 (0%)									
(2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%							
	/50 (2%) . Tumor (M or B), Bahoma, Trichoepitheli /50 (12%) (12%) /50 (6%) /50 (6%) Desarcoma, or Fibrous /50 (8%) (50 (2%) Lus Histiocytoma /50 (2%)	/50 (2%) Mean 2% . Tumor (M or B), Basal Cell Adenoma, homa, Trichoepithelioma /50 (12%) (12%) Mean 12% /50 (6%) Mean 6% Desarcoma, or Fibrous Histiocytoma /50 (8%) Mean 8% /50 (2%) Mean 2% us Histiocytoma /50 (2%)	/50 (2%) (2%) Mean 2% SD 0% Tumor (M or B), Basal Cell Adenoma, homa, Trichoepithelioma /50 (12%) (12%) Mean 12% SD 0% /50 (6%) (6%) Mean 6% SD 0% Desarcoma, or Fibrous Histiocytoma /50 (8%) (8%) Mean 8% SD 0% /50 (2%) (2%) Mean 2% SD 0%	/50 (2%) Mean 2% SD 0% Total . Tumor (M or B), Basal Cell Adenoma, homa, Trichoepithelioma /50 (12%) (12%) Mean 12% SD 0% Total /50 (6%) Mean 6% SD 0% Total . Desarcoma, or Fibrous Histiocytoma /50 (8%) (8%) Mean 8% SD 0% Total /50 (2%) (2%) Mean 2% SD 0% Total	1/50 (2%) 1/50 (4%) 1/50 (2%) 1/50 (4%) 1/50 (2%) 1/50 (4%) 1/50 (2%) 1/50 (4%) 1/50 (2%) 1/50 (2%) 1/50 (2%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (2%) 1/50 (2%) 1/50 (0%) 1/50 (0%) 1/50 (2%) 1/50 (2%) 1/50 (2%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (2%) 1/50 (2%) 1/50 (2%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (2%) 1/50 (2%) 1/50 (2%) 1/50 (0%) 1/50	1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) Mean 2%							

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 166

			Male			Female			
#Skin: Fibrous Histiocytoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skin: Hemangiosarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skin: Keratoacanthoma Overall Incidence	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skin: Lipoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skin: Liposarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skin: Neural Crest Tumor Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Overall Incidence

Overall Incidence

Overall Incidence

Overall Incidence

Overall Incidence

Overall Incidence

.....

Schwannoma Benign

Schwannoma Malignant

#Skin:

#Skin:

#Skin:

#Skin: Sarcoma

#Skin:

#Skin:

Toxicology Data Management System

Contract/Lab: All Laboratories

Total

Total

Total

Total

Total

Total

Neurofibrosarcoma or Schwannoma (malignant or NOS)

0/50

0/50 (0%)

0/50

0/50 (0%)

0/50

0/50 (0%)

0/50

0/50 (0%)

0/50

0/50 (0%)

0/50

0/50 (0%)

(0%)

(0%)

(0%)

(0%)

(0%)

Mean 0%

Mean 0%

Length of Study: CHRONIC

Neurofibroma or Schwannoma benign

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

SD 0%

SD 0%

Male **Female** 0/50 (0%)Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%)Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) 0/50 (0%)Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%)Mean 0% SD 0% Total Mean 0% SD 0% 0/50 (0%)

0/50

0/50

0/50 (0%)

0/50 (0%)

Total

Total

(0%)

(0%)

Mean 0%

Mean 0%

SD 0%

SD 0%

Page: 167

*: Denominator is number	er of animals with tissues	examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 168

			Male				Female	
#Skin: Squamous Cell Carcinoma Overall Incidence	I Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma or Carcinoma	ı, Basal Cell C		us Tumor (malignan	t or NOS),		······		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma	-	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma,	Papilloma, S	quamous Cell Carcinoma 5/50 (10%)	a or Keratoacanthon	na		0/50 (0%)		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma,	Papilloma, o	r Keratoacanthoma 5/50 (10%)				0/50 (0%)		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 169

			Male			Female			
#Skin: Trichoepithelioma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skin: Sebaceous Gland: Adenoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skin: Sebaceous Gland: Carcinoma or Adenoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Spinal Cord: Glioma Malignant Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Stomach, Glandular: Carcinoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Stomach, Glandular: Carcinoma or Adenoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 170

#Stomach, Glandular: Sarcoma Overall Incidence			Male				Female	
	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Testes: Adenoma		35/50 (70%)						
Overall Incidence	Total	35/50 (70%)	Mean 70%	SD 0%				
*Testes: Hemangioma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
*Thymus: Thymoma Benign Overall Incidence	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant		0/49 (0%)				0/49 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma NOS		0/49 (0%)				0/49 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 171

			Male				Female Mean 0% SD 0% Mean 20% SD 0% Mean 2% SD 0% Mean 22% SD 0%			
*Thymus: Thymoma: Benign, Malignant, NOS 0/49 (0%) 0/49 (0%)										
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%		
*Thyroid Gland: C-Cell: Adenoma										
Overall Incidence	Total	12/50 (24%) 12/50 (24%)	Mean 24%	SD 0%	Total	10/50 (20%) 10/50 (20%)	Mean 20%	SD 0%		
*Thyroid Gland: C-Cell: Carcinoma										
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		13/50 (26%)				11/50 (22%)				
Overall Incidence	Total	13/50 (26%)	Mean 26%	SD 0%	Total	11/50 (22%)				
*Thyroid Gland: Follicular C Adenoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Thyroid Gland: Follicular C Carcinoma						0/50 (00/)				
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 172

			Male				Female		
*Thyroid Gland: Follicular C Carcinoma or Adenoma	Cell:	1/50 (2%)							
		•	,			0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Tongue: Squamous Cell Carcinom	na								
		0/50 (0%	,			0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Tongue: Squamous Cell Carcinom	-	0/50 (0%	,			0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Tongue: Squamous Cell Papilloma				SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Tongue:				SD 0% SD 0%	Total Total		Mean 0% Mean 0%	SD 0% SD 0%	
#Tongue: Squamous Cell Papilloma	a Total	0/50 (0% 0/50 (0%)	%) Mean 0%			0/50 (0%) 0/50 (0%)			
#Tongue: Squamous Cell Papilloma Overall Incidence #Tooth: Adamantinoma Malignan	Total	0/50 (0% 0/50 (0%) 0/50 (0%	%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Tongue: Squamous Cell Papilloma Overall Incidence #Tooth:	a Total	0/50 (0% 0/50 (0%)	%) Mean 0%			0/50 (0%) 0/50 (0%)			
#Tongue: Squamous Cell Papilloma Overall Incidence #Tooth: Adamantinoma Malignan	Total	0/50 (0% 0/50 (0%) 0/50 (0%	%) Mean 0% %) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 173

Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Male **Female** *Urinary Bladder: Carcinoma or Papilloma 0/50 (0%)0/50 (0%)0/50 (0%) SD 0% SD 0% **Overall Incidence** Total Mean 0% Total 0/50 (0%) Mean 0% *Urinary Bladder: Hemangiosarcoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Urinary Bladder: **Papilloma** 0/50 (0%)0/50 (0%)SD 0% **Overall Incidence** Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% #Uterus: Adenoma 0/50 (0%)**Overall Incidence** SD 0% Total 0/50 (0%) Mean 0% #Uterus: Carcinoma 1/50 (2%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% **#Uterus:** Leiomyosarcoma 1/50 (2%)

Total

1/50 (2%)

Mean 2%

SD 0%

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 174

Report Date: 06/05/2013

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Uterus: Polyp Stromal** 8/50 (16%) **Overall Incidence** Total 8/50 (16%) Mean 16% SD 0% **#Uterus:** Sarcoma 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% #Uterus: Sarcoma Stromal 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% #Uterus: Sarcoma Stromal or Polyp Stromal 8/50 (16%) **Overall Incidence** SD 0% Total 8/50 (16%) Mean 16% #Uterus: **Schwannoma Malignant**

0/50

0/50 (0%)

Total

(0%)

Mean 0%

SD 0%

Polyp 1/50 (2%)

 Overall Incidence
 Total
 1/50 (2%)
 Mean 2%
 SD 0%

Overall Incidence

#Vagina:

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 175

			Male				Female	
#Vagina: Sarcoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Vagina: Schwannoma Malignant								
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma		4/50 (00)				0/50 (00/)		
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups Route: PERINATAL AND POSTNATAL Vehicle: FEED

Page: 176

Report Date: 06/05/2013

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical			
					Male					
Battelle Columbus Laboratory	059901305	05/12/05	726	50(3)	36(685)	522.7	Styrene-acrylonitrile trimer			
	Female									
Battelle Columbus Laboratory	059901305	05/13/05	727	50(5)	41(699)	371.2	Styrene-acrylonitrile trimer			

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 177

			Male			Female			
#All Organs: Benign Tumors									
		46/50 (92%)				42/50 (84%)			
Overall Incidence	Total	46/50 (92%)	Mean 92%	SD 0%	Total	42/50 (84%)	Mean 84%	SD 0%	
#All Organs: Malignant Tumors									
		22/50 (44%)				19/50 (38%)			
Overall Incidence	Total	22/50 (44%)	Mean 44%	SD 0%	Total	19/50 (38%)	Mean 38%	SD 0%	
#All Organs: Malignant and Benign Tu	ımors	49/50 (98%)				44/50 (88%)			
Overall Incidence	Total	49/50 (98%)	Mean 98%	SD 0%	Total	44/50 (88%)	Mean 88%	SD 0%	
#All Organs: Hemangioma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#All Organs: Hemangiosarcoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#All Organs: Hemangiosarcoma or He	emangioma	0/50 (00)				0/50 /00/			
Overall Incidence	Total	0/50 (0%)	Maan 00/	CD 00/	Total	0/50 (0%)	Maan 00/	CD 00/	
	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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Report Date: 06/05/2013

SD 0%

SD 0%

			Male	Female				
#All Organs: Histiocytic Sarcoma								
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs:								
	c, Monocytic, Mo	ononuclear, or Undiffere	ntiated					
		15/50 (30%)				13/50 (26%)		
Overall Incidence	Total	15/50 (30%)	Mean 30%	SD 0%	Total	13/50 (26%)	Mean 26%	SD 0%
#All Organs:								
Malignant Lymphoma:	Histiocytic, Lym	phocytic, Mixed, NOS, o	r Undifferentiated Ce	II Type				
		0/50 (0%)				0/50 (0%)		
			• • • • • • • • • • • • • • • • • • • •	OD 00/		0/50 (00/)	Mean 0%	CD 00/
	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)		SD 0%
		,		02 070		,		
Overall Incidence #All Organs: Mesothelioma: Benign,				02 070		,		
				02 070		,		

SD 0%

SD 0%

0/50

0/50

0/50 (0%)

0/50 (0%)

Total

Total

(0%)

(0%)

Mean 0%

Mean 0%

Total

......

Total

4/50

4/50 (8%)

0/50

0/50 (0%)

(8%)

(0%)

Mean 8%

Mean 0%

Mesothelioma: Malignant

Overall Incidence

Overall Incidence

#All Organs: Osteoma

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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				Male				Female	e	
#All Organs: Osteosarcoma		0/50 ((0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	0 70)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#All Organs: Osteosarcoma or Osteoma		0/50 ((0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Adrenal Cortex: Adenoma		0/50 ((0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	0 70)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
*Adrenal Cortex: Carcinoma		0/50 ((0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	0 70)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Benign		4/50 (8	00/\	••••••			0/50 (0%)			
Overall Incidence	Total	4/50 (8%)	8%)	Mean 8%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Comple	ex	0/50 ((0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	0,0,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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				Male				Female			
*Adrenal Medulla: Pheochromocytoma Malignant 0/50 (0%) 1/50 (2%)											
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
*Adrenal Medulla: Pheochromocytoma: Beniq	gn, Complex,	-	(8%)				1/50 (2%)				
Overall Incidence	Total	4/50 (8%)	(0%)	Mean 8%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
#Blood Vessel: Leiomyosarcoma		0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Bone: Chordoma Overall Incidence	Total		(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Bone:		` ,					(,		30 0%		
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Bone: Osteosarcoma		0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	(-/0)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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		Male Female				0/50 (0%) 0% Total 0/50 (0%) Mean 0% 1/50 (2%) 0% Total 1/50 (2%) Mean 2% 0/50 (0%) 0% Total 0/50 (0%) Mean 0% 0/50 (0%) 0% Total 0/50 (0%) 0% Mean 0%		
#Bone: Osteosarcoma or Osteoma	a							
Overall Incidence	Total	0/50 (0° 0/50 (0%)	Mean 0%	SD 0%		0/50 (0%)		SD 0%
*Brain: Glioma								
Overall Incidence	Total	0/50 (0° 0/50 (0%)	%) Mean 0%	SD 0%	Total	` '	Mean 2%	SD 0%
*Brain: Glioma Benign		0/50 (0 ⁴	0/)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
*Brain: Glioma Malignant		0/50 (0	%)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
*Brain: Oligodendroglioma, Gliom		toma						
Overall Incidence	Total	0/50 (0° 0/50 (0%)	%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Brain: Osteosarcoma		0/50 /0	0(1)			0/50 (09/.)		
Overall Incidence	Total	0/50 (0° 0/50 (0%)	%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Adenoma

Carcinoma

Sarcoma

#Ear:

#Eye:

Melanoma Benign

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Male **Female** *Clitoral/Preputial Gland: 1/50 (2%)3/50 (6%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total 3/50 (6%) Mean 6% SD 0% *Clitoral/Preputial Gland: 1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Clitoral/Preputial Gland: Carcinoma or Adenoma 2/50 (4%)3/50 (6%)**Overall Incidence** Total 2/50 (4%) Mean 4% SD 0% Total 3/50 (6%) Mean 6% SD 0% *Clitoral/Preputial Gland: 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total Mean 0% SD 0% 0/50 (0%) **Neural Crest Tumor** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%

0/50

0/50 (0%)

Total

(0%)

Mean 0%

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Report Date: 06/05/2013

SD 0%

0/50

(0%)

Mean 0%

SD 0%

Overall Incidence Total 0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male			Female				
#Eye: Melanoma Malignant		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Harderian Gland: Adenoma		0/50 (0%)				0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Harderian Gland: Carcinoma		0/50 (00()				0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Harderian Gland: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Heart: Schwannoma Benign										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Heart: Schwannoma Malignant		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Intestine Large: Colon/Rectu Adenoma	m:	1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectu Carcinoma or Adenoma	m:							
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Leiomyoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Schwannoma Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Adenoma						0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS **Strain:** F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male		0/50 (0%) Total 0/50 (0%) Mean 0% SD 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0/50 (0%) Total 0/50 (0%) Mean 0% SD			
#Intestine Small: Jejunum: Leiomyoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspo Adenoma	ecified:							
		0/50 (0%)				` '		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%		, ,		SD 0%
#Intestine Small: Site Unspe Carcinoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%		` ,		SD 0%
#Intestine Small: Site Unspe Carcinoma or Adenoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspo Leiomyoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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		Male				Female				
#Intestine Small: Site Unsp	pecified:									
•		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Site Uns Schwannoma Malignant	pecified:									
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Islets, Pancreatic: Adenoma		0/50 (0%)				1/50 (2%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
*Islets, Pancreatic: Carcinoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Islets, Pancreatic: Carcinoma or Adenoma		0/50 (0%)				1/50 (2%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
Kidney: Pelvis and Transi Papilloma	tional Epitheliu	m: 0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Vehicle: FEED

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Report Date: 06/05/2013

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: PERINATAL AND POSTNATAL

Length of Study: CHRONIC

Male **Female** *Kidney: Renal Tubule: Adenoma 1/50 (2%)0/50 (0%)1/50 (2%) **Overall Incidence** Total Mean 2% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Carcinoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Carcinoma or Adenoma 1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Lipoma 0/50 (0%)0/50 (0%)Overall Incidence Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: **Mesenchymal Tumor Malignant** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Sarcoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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				Male				Female	
*Liver: Hepatocellular Adenoma									
			(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma c	or Hepatobla		(00/)				0/50 (0%)		
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma c	or Hepatocel		(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma,	Hepatocellu		Hepatobla	astoma			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(-7-)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Ito Cell Tumor Benign		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(0 /0)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N Length of Study: CHRONIC Tumor Incidence for Selected Control Animal Groups Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male			Female				
*Lung: Alveolar/Bronchiolar A	Adenoma	1/50 (2%)				0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Lung: Alveolar/Bronchiolar C	Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Lung: Alveolar/Bronchiolar C	Carcinoma or Alve	eolar/Bronchiolar Adend 1/50 (2%)	ma			0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Lung: Fibrosarcoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Mammary Gland: Adenolipoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Mammary Gland: Adenoma		0/50 (00/)				0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male Female					
#Mammary Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
#Mammary Gland: Carcinoma or Adenoma		0/50 (00)				0/50 (40/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
#Mammary Gland: Fibroadenoma		4/50 (00()				00/50 /700/		
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	36/50 (72%) 36/50 (72%)	Mean 72%	SD 0%
#Mammary Gland: Fibroma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma o	or Adenoma			•••••				
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	36/50 (72%) 36/50 (72%)	Mean 72%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma, (36/50 (72%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	36/50 (72%)	Mean 72%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male Female				0/50 (0%) Total 0/50 (0%) Mean 0% SD 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0/50 (0%) Total 0/50 (0%) Mean 0% SD	
#Mesentery: Fibrous Histiocytoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mesentery: Schwannoma Malignar	nt	0/50 (00)				0/50 (00)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
*Nose: Adenoma		0/50 (00)				0/50 (00)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Papilloma Squamous o	a, Tongue, Phary	nx, Tooth, Gingiva): 0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%		0/50 (0%)		SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcine	a, Tongue, Phary							
-		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%		` ,		SD 0%
#Oral Cavity (Oral Mucos	a, Tongue, Phary							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#Oral Mucosa: Squamous Cell Carcinoma								SD 0% SD 0% SD 0% SD 0%
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	
#Oral Mucosa: Squamous Cell Papilloma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Cystadenoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Fibrosarcoma						0/50 (00/)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor Beniq								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor Malig	ınant							
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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Mean 2%

SD 0%

Report Date: 06/05/2013

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: PERINATAL AND POSTNATAL

Length of Study: CHRONIC

Vehicle: FEED

Male Female *Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% *Ovary: **Granulosa-Theca Tumor Malignant** 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% *Ovary: **Schwannoma Malignant** 0/50 (0%)Overall Incidence Total 0/50 (0%) Mean 0% SD 0% *Ovary: **Sertoli Cell Tumor Malignant** 0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% 0/50 (0%) *Ovary: **Tubulostromal Adenoma** 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% *Pancreas: Adenoma 1/50 (2%)1/50 (2%)

SD 0%

Total

1/50 (2%)

Total

1/50 (2%)

Mean 2%

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N Length of Study: CHRONIC Tumor Incidence for Selected Control Animal Groups Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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	Male Female					1/50 (2%) Total 1/50 (2%) Mean 2% SD 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0/48 (0%) Total 0/48 (0%) Mean 0% SD 22/50 (44%) Total 22/50 (44%) Mean 44% SD		
*Pancreas: Carcinoma or Adenoma								
Overell lesidence	Tatal	1/50 (2%)	Mana 20/	CD 00/	Tatal	` '	Mana 20/	CD 00/
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	ı otal	1/50 (2%)	Wean 2%	SD 0%
*Pancreas: Mixed Tumor Benign								
		1/50 (2%)				` '		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Parathyroid Gland: Adenoma		0/25 (00/)				0/40 (00/)		
Overall Incidence	Total	0/35 (0%) 0/35 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
*Pituitary Gland: Pars Distali Adenoma Overall Incidence	is or Unspeci Total	fied Site: 16/50 (32%) 16/50 (32%)	Mean 32%	SD 0%	Total	22/50 (44%) 22/50 (44%)		SD 0%
*Pituitary Gland: Pars Distali Carcinoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Distali Carcinoma or Adenoma								
		16/50 (32%)				22/50 (44%)		
Overall Incidence	Total	16/50 (32%)	Mean 32%	SD 0%	Total	22/50 (44%)	Mean 44%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS **Strain**: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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	Male				Female			
alis or Unspecif	ied Site:							
	0/50 (0%)				0/50 (0%)			
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
rmedia:								
	0/50 (0%)				0/50 (0%)			
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
rmedia:	0/50 (00)				0/50 (00)			
Total	` '	Maan 00/	CD 00/	Total	` '	Maan 00/	SD 0%	
	` '		3D 0%	ı Olal	0/50 (0%)	iviean 0%	3D 0%	
vosa:	0/50 (0%)				0/50 (0%)			
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
	0/50 (0%)							
Total	0/50 (0%)	Mean 0%	SD 0%					
	0/50 (09/)							
Total	, ,	Mean 0%	SD 0%					
	Total Total Total Total Total Total Total	Total 0/50 (0%) rmedia: 0/50 (0%) Total 0/50 (0%) rmedia: 0/50 (0%) Total 0/50 (0%) //osa: 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) 0/50 (0%)	Alis or Unspecified Site: 0/50 (0%)	Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Tmedia: 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%	Alis or Unspecified Site: Total	Alis or Unspecified Site: Total	Alis or Unspecified Site: Total 0/50 (0%)	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male		Female				
*Salivary Glands: Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Salivary Glands: Carcinoma or Adenoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Salivary Glands: Sarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Salivary Glands: Schwannoma Malignant		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Seminal Vesicle: Adenoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%					
#Skeletal Muscle: Fibrous Histiocytoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

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Report Date: 06/05/2013

SD 0%

Mean 0%

Tumor Incidence for Selected Control Animal Groups

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Male **Female #Skeletal Muscle:** Lipoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Skin: **Basal Cell Adenoma** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Skin: Basal Cell Adenoma or Basosquamous Tumor Benign 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Skin: Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total Mean 0% SD 0% 0/50 (0%) #Skin: **Basal Cell Carcinoma** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) 0/50 (0%)0/50 (0%)

SD 0%

Total

0/50 (0%)

Total

0/50 (0%)

Mean 0%

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#Skin: Basal Cell Carcinoma, NOS), or Trichoepithel		oma, Basosquamous Tu	mor (benign, maligna	ant or				
,, ,		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin:								
		a, Basosq. Tumor (M or ratoacanthoma, Trichoe		ma,		4/50 (00/)		
Overall Incidence	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
		4/50 (6%)	0%	 		1/50 (2%)	2%	
#Skin: Fibroma								
		5/50 (10%)				0/50 (0%)		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Fibroma, Fibrosarcom	a, Sarcoma, Myx	oma, Myxosarcoma, or F 5/50 (10%)	ibrous Histiocytoma	1		0/50 (0%)		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Fibrosarcoma								
	-	0/50 (0%)		00.00/		0/50 (0%)		00.00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Fibrosarcoma, Sarcon	na, Myxosarcoma	ı, or Fibrous Histiocytom	na					
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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		Male Female							
#Skin: Fibrous Histiocytoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Hemangiosarcoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skin: Keratoacanthoma				•••••					
		2/50 (4%)				1/50 (2%)			
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Skin: Lipoma		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Liposarcoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Neural Crest Tumor		0/50 (09/)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
Overall incluence	i Olai	0/30 (0%)	IVICALI U70	3D 0%	TOLAI	0/30 (0%)	IVICALI U%	3D 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male		Female 0/50 (0%) Mean 0% SD 0% 1/50 (2%) Mean 2% SD 0% 1/50 (2%) Mean 2% SD 0% 1/50 (2%) Mean 2% SD 0% 0/50 (2%) Mean 2% SD 0% 0/50 (0%) Mean 0% SD 0%			
#Skin: Neurofibroma or Schwa	nnoma benign							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Skin:								
Neurofibrosarcoma or \$	Schwannoma (m	•						
		0/50 (0%)				` '		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` '		
#Skin:								
-	urofibroma, or S	chwannoma (benign, ma	lignant or NOS)					
•	,	0/50 (0%)	,			1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	, ,		
#Skin:								
Sarcoma								
		0/50 (0%)				` '		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	, ,	Mean 0%	SD 0%
#Skin:								
Schwannoma Benign		0/50 (0%)				0/50 (0%)		
	-	` ,	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
Overall Incidence	Lotal	0/50 (0%)						
Overall Incidence	Total	0/50 (0%)						
Overall Incidence #Skin: Schwannoma Malignan		0/50 (0%)	iviean 0%		····			
#Skin:		0/50 (0%)	wean 0%	35 0/8	1000	1/50 (2%)		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N Length of Study: CHRONIC Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male		O/50 (0%) Total O/50 (0%) Mean 0% SD 0% O/50 (0%) Total O/50 (0%) Mean 0% SD 0% O/50 (0%) Total O/50 (0%) Mean 0% SD 0% 1/50 (2%)			Female				
#Skin: Squamous Cell Carcino	oma											
•		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
Skin:												
Squamous Cell Carcino or Carcinoma	oma, Basal Cell C	Carcinoma, Basosquamo	us Tumor (malignar	nt or NOS),								
		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skin: Squamous Cell Papillo	ma			•••••	•••••	•••••						
		2/50 (4%)				0/50 (0%)						
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skin: Squamous Cell Papillo	ma or Papilloma			•••••		•••••						
	•	2/50 (4%)				0/50 (0%)						
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skin: Squamous Cell Papillo	ma, Papilloma, S	quamous Cell Carcinom	a or Keratoacanthor	ma								
		4/50 (8%)				1/50 (2%)						
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%				
#Skin: Squamous Cell Papillo	ma, Papilloma, o	r Keratoacanthoma 4/50 (8%)				1/50 (2%)						
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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(0%)

Mean 0%

0/50

Total

0/50 (0%)

Report Date: 06/05/2013

SD 0%

			Male				Female	
#Skin: Trichoepithelioma						,		
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma								
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Spinal Cord: Glioma Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma or Adenoma								

SD 0%

Total

(0%)

Mean 0%

0/50

0/50 (0%)

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F 344/N

Toxicology Data Management System

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Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups Species: RATS

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Length of Study: CHRONIC

			Male			0/50 (0%) Total 0/50 (0%) Mean 0% SD 09		
#Stomach, Glandular: Sarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%		` '		SD 0%
*Testes: Adenoma		41/50 (82%)						
Overall Incidence	Total	41/50 (82%)	Mean 82%	SD 0%				
*Testes: Hemangioma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
*Thymus: Thymoma Benign		1/48 (2%)						
Overall Incidence	Total	1/48 (2.08%)	Mean 2.08%	SD 0%		0/50 (0%)		SD 0%
*Thymus: Thymoma Malignant								
Overall Incidence	Total	1/48 (2%) 1/48 (2.08%)	Mean 2.08%	SD 0%	Total	,	Mean 2%	SD 0%
*Thymus: Thymoma NOS		0/48 (0%)				0/50 (0%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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Report Date: 06/05/2013

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Length of Study: CHRONIC

			Male		Female				
*Thymus: Thymoma: Benign, Malig	nant, NOS	2/48 (4%)				1/50 (2%)			
Overall Incidence	Total	2/48 (4.17%)	Mean 4.17%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
*Thyroid Gland: C-Cell: Adenoma		12/50 (24%)				6/50 (12%)			
Overall Incidence	Total	12/50 (24%)	Mean 24%	SD 0%	Total	6/50 (12%)	Mean 12%	SD 0%	
*Thyroid Gland: C-Cell: Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Thyroid Gland: C-Cell: Carcinoma or Adenoma									
Overall Incidence	Total	12/50 (24%) 12/50 (24%)	Mean 24%	SD 0%	Total	6/50 (12%) 6/50 (12%)	Mean 12%	SD 0%	
*Thyroid Gland: Follicular (Adenoma									
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
*Thyroid Gland: Follicular (Carcinoma	Cell:				•••••				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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				Male					
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma	:								
		1/50	(2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Tongue: Squamous Cell Carcinoma									
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma o	or Papilloma	a Squamous 0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	` '	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tooth: Adamantinoma Malignant									
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Carcinoma									
		1/50	(2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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				Male			Female				
*Urinary Bladder: Carcinoma or Papilloma		1/50 (2	2%)				0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	270)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Urinary Bladder: Hemangiosarcoma		0/50 ((0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	U70)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Urinary Bladder: Papilloma		0/50 //	00()				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Uterus: Adenoma							0/50 (09/)				
Overall Incidence						Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Uterus: Carcinoma		•••••					0/50 (00/)				
Overall Incidence						Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Uterus: Leiomyosarcoma											
Overall Incidence						Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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	Male			Female	
#Uterus: Polyp Stromal					
Overall Incidence		Total	6/50 (12%) 6/50 (12%)	Mean 12%	SD 0%
#Uterus: Sarcoma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma Stromal					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal					
Overall Incidence		Total	6/50 (12%) 6/50 (12%)	Mean 12%	SD 0%
#Uterus: Schwannoma Malignant					
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Vagina: Polyp					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups
Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 208

			Male			0/50 (0%) otal 0/50 (0%) Mean 0% SD 0% 0/50 (0%) otal 0/50 (0%) Mean 0% SD 0% 0/50 (0%)		
#Vagina: Sarcoma								
Overall Incidence					Total	` '	Mean 0%	SD 0%
#Vagina: Schwannoma Malignant								
Overall Incidence					Total	` '	Mean 0%	SD 0%
#Zymbal's Gland: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma						0/50 (00/)		
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)		SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 209 Report Dat

Report Date: 06/05/2013

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical		
Male									
Southern Research Institute	058813307	01/18/05	729	50(1)	23(681)	516.1	Trimethylolpropane triacrylate		
Female									
Southern Research Institute	058813307	01/18/05	731	50(1)	27(688)	352.8	Trimethylolpropane triacrylate		

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE **Page:** 210

			Male	Female				
#All Organs: Benign Tumors		48/50 (96%)				43/50 (86%)		
Overall Incidence	Total	48/50 (96%)	Mean 96%	SD 0%	Total	43/50 (86%)	Mean 86%	SD 0%
#All Organs: Malignant Tumors		30/50 (60%)				21/50 (42%)		
Overall Incidence	Total	30/50 (60%)	Mean 60%	SD 0%	Total	21/50 (42%)	Mean 42%	SD 0%
#All Organs: Malignant and Benign Tu		50/50 (100%)				47/50 (94%)		
Overall Incidence	Total	50/50 (100%)	Mean 100%	SD 0%	Total	47/50 (94%)	Mean 94%	SD 0%
#All Organs: Hemangioma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
					Total			
#All Organs: Hemangiosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma or He	mangioma	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Page: 211

Report Date: 06/05/2013

SD 0%

Mean 0%

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #All Organs: **Histiocytic Sarcoma** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #All Organs: Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated 26/50 (52%)12/50 (24%)**Overall Incidence** Total 26/50 (52%) Mean 52% SD 0% Total 12/50 (24%) Mean 24% SD 0% #All Organs: Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type 0/50 (0%)0/50 (0%)Overall Incidence Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #All Organs: Mesothelioma: Benign, Malignant, NOS 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total Mean 0% SD 0% 0/50 (0%) **#All Organs:** Mesothelioma: Malignant 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #All Organs: Osteoma 0/50 (0%)0/50 (0%)

SD 0%

Total

0/50 (0%)

Mean 0%

Total

0/50 (0%)

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 212

			Male	Female				
#All Organs: Osteosarcoma		2/50 (4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma or Osteoma								
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Adenoma		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Carcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Benign								
Overall Incidence	Total	11/49 (22%) 11/49 (22.45%)	Mean 22.45%	SD 0%	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Comple						0/49 /00/		
Overall Incidence	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 213

			Male		Female						
*Adrenal Medulla: Pheochromocytoma Malignant											
•	-	1/49 (2%)				0/48 (0%)					
Overall Incidence	Total	1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%			
*Adrenal Medulla: Pheochromocytoma: B											
i neocinomocytoma. B	enign, complex	12/49 (24%)				0/48 (0%)					
Overall Incidence	Total	12/49 (24.49%)	Mean 24.49%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%			
#Blood Vessel: Leiomyosarcoma											
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Bone: Chordoma											
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Bone: Osteoma											
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Bone: Osteosarcoma											
		2/50 (4%)				0/50 (0%)					
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Animai Groups

Page: 214

			Male	Female				
#Bone: Osteosarcoma or Osteoma								
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Brain: Glioma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Brain: Glioma Benign		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Brain: Glioma Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma, Glioma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Brain: Osteosarcoma		0/50 (00/)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 215

*Clitoral/Preputial Gland: Adenoma			Male		Female			
		3/50 (6%)				4/50 (8%)		
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	4/50 (8%)	Mean 8%	SD 0%
*Clitoral/Preputial Gland: Carcinoma								
		0/50 (0%)				7/50 (14%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	7/50 (14%)	Mean 14%	SD 0%
*Clitoral/Preputial Gland: Carcinoma or Adenoma		0/50 (00/)				40/50 (000/)		
Overell lesidence	Tatal	3/50 (6%)	Mann 00/	CD 00/	Tatal	10/50 (20%)	Mana 200/	CD 00/
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	10/50 (20%)	Mean 20%	SD 0%
*Clitoral/Preputial Gland: Sarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Ear: Neural Crest Tumor								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Eye: Melanoma Benign								
		0/50 (0%)		25		0/50 (0%)		00.007
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 216

#Eye: Melanoma Malignant			Male	Female				
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Harderian Gland: Adenoma		0/50 (0%)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma		0/50 (00()				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Benign								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 217

Report Date: 06/05/2013

SD 0%

			Male				Female	
#Intestine Large: Colon/Rect	um:	0/50 (00/)				0/50 (00)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Recto Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Leiomyoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Schwannoma Malignant Overall Incidence		0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Adenoma		0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

SD 0%

0/50

Total

0/50 (0%)

(0%)

Mean 0%

Total

(0%)

Mean 0%

0/50

0/50 (0%)

Carcinoma

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Intestine Small: Jejunum: Leiomyoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma								
O	T-1-1	0/50 (0%)	Maran 00/	OD 00/	T-1-1	0/50 (0%)	Maran 00/	OD 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspo Adenoma	ecified:							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspo Carcinoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspo				•••••				
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspo Leiomyoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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Mean 0%

SD 0%

Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Male **Female** #Intestine Small: Site Unspecified: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/50 (0%) **Overall Incidence** Total Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified: **Schwannoma Malignant** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Islets, Pancreatic: Adenoma 18/50 (36%)3/50 (6%)**Overall Incidence** Total 18/50 (36%) Mean 36% SD 0% Total 3/50 (6%) Mean 6% SD 0% *Islets, Pancreatic: Carcinoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total Mean 0% SD 0% 0/50 (0%) *Islets, Pancreatic: Carcinoma or Adenoma 18/50 (36%)3/50 (6%)**Overall Incidence** Total 18/50 (36%) Mean 36% SD 0% Total 3/50 (6%) Mean 6% SD 0% *Kidney: Pelvis and Transitional Epithelium: **Papilloma** 0/50 (0%)0/50 (0%)

SD 0%

Total

0/50 (0%)

Total

0/50 (0%)

Mean 0%

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Kidney: Renal Tubule: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%) **Overall Incidence** Total Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Carcinoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Lipoma 0/50 (0%)0/50 (0%)Overall Incidence Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: **Mesenchymal Tumor Malignant** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Sarcoma 0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 1/50 (2%) Mean 2% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

*Liver:

*Liver:

*Liver:

*Liver:

*Liver:

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Hepatocellular Adenoma

Hepatocellular Carcinoma

.....

Overall Incidence

Overall Incidence

Overall Incidence

Overall Incidence

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Male **Female** 1/50 (2%)0/50 (0%)Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0% SD 0% 1/50 (2%)0/50 (0%)Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0% SD 0% Hepatocellular Carcinoma or Hepatoblastoma 1/50 (2%)0/50 (0%)Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0% SD 0% Hepatocellular Carcinoma or Hepatocellular Adenoma 2/50 (4%)0/50 (0%)Total 2/50 (4%) Mean 4% SD 0% Total Mean 0% SD 0% 0/50 (0%) Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma 2/50 (4%)0/50 (0%)2/50 (4%) Mean 4% SD 0% Total 0/50 (0%) Mean 0% SD 0%

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Report Date: 06/05/2013

SD 0%

Mean 0%

Overall Incidence Total

*Liver:

Ito Cell Tumor Benign

0/50 (0%)0/50 (0%)

Overall Incidence Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 222

			Male				Female					
*Lung: Alveolar/Bronchiolar Adenoma 1/50 (2%) 0/50 (0%)												
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
*Lung: Alveolar/Bronchiolar C	Carcinoma											
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
*Lung: Alveolar/Bronchiolar C	Carcinoma or Alve	eolar/Bronchiolar Aden 2/50 (4%)	oma			0/50 (0%)						
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Lung: Fibrosarcoma		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Mammary Gland: Adenolipoma												
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Mammary Gland: Adenoma	•••••	0/50 (0%)				4/50 (8%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	4/50 (8%)	Mean 8%	SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

#Mammary Gland: Carcinoma

Overall Incidence

#Mammary Gland:

Overall Incidence

#Mammary Gland: Fibroadenoma

Carcinoma or Adenoma

.....

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Male **Female** 3/50 (6%)Mean 0% SD 0% Total 3/50 (6%) Mean 6% SD 0% 6/50 (12%) Mean 0% SD 0% Total 6/50 (12%) Mean 12% SD 0%

22/50 (44%)

22/50 (44%)

Total

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Mean 44%

Mean 50%

Report Date: 06/05/2013

SD 0%

SD 0%

Overall Incidence
#Mammary Gland:

Fibroma

0/50 (0%)0/50 (0%)

SD 0%

Overall Incidence Total 0/50 (0%) Mean 0% SD 0% Total Mean 0% SD 0% 0/50 (0%)

#Mammary Gland:

Fibroma, Fibroadenoma or Adenoma

1/50 (2%)25/50 (50%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total 25/50 (50%) Mean 50% SD 0%

#Mammary Gland:

Fibroma, Fibroadenoma, Carcinoma, or Adenoma

1/50 (2%)25/50 (50%)

Overall Incidence Total 1/50 (2%) Mean 2% SD 0% 25/50 (50%) Total

Mean 2%

0/50

0/50 (0%)

0/50

0/50 (0%)

1/50

1/50 (2%)

(0%)

(0%)

(2%)

*: Denominator is number of animals with tissues examined microscopically

Total

Total

Total

#: Denominator is number of animals necropsied

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 224 Report Date: 06/05/2013

			Male			Female			
#Mesentery: Fibrous Histiocytoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Mesentery: Schwannoma Malignan	t								
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Nose: Adenoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Oral Cavity (Oral Mucos Papilloma Squamous o	a, Tongue, Phary					0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Oral Cavity (Oral Mucos Squamous Cell Carcing	a, Tongue, Phary								
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Oral Cavity (Oral Mucos	a, Tongue, Phary					0/50 (0%)			
		(= /0)				2. 2 2 (0 /0)			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Page: 225

Mean 2%

SD 0%

Report Date: 06/05/2013

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N Length of Study: CHRONIC

Route: SKIN Vehicle: ACETONE

Male **Female #Oral Mucosa: Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%) SD 0% **Overall Incidence** Total Mean 0% SD 0% Total 0/50 (0%) Mean 0% **#Oral Mucosa: Squamous Cell Papilloma** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Ovary: Cystadenoma 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% *Ovary: Fibrosarcoma 0/50 (0%)SD 0% **Overall Incidence** Total 0/50 (0%) Mean 0% *Ovary: **Granulosa Cell Tumor Benign** 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% **Granulosa Cell Tumor Malignant** 1/50 (2%)**Overall Incidence**

Total

1/50 (2%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 226

			Male				Female	
*Ovary: Granulosa Cell Tumor: Ber	nign, Maligna	nt, NOS				(201)		
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Ovary: Granulosa-Theca Tumor M								
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Schwannoma Malignant						0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Sertoli Cell Tumor Maligna					•••••	0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Tubulostromal Adenoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Pancreas: Adenoma		1/50 /20/)			•••••			
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 227

			Male			Female					
*Pancreas: Carcinoma or Adenoma 1/50 (2%) Overall Incidence Total 1/50 (2%) Overall Incidence 1/50 (0%) Overall Incidence 1/50 (0%) Overall Incidence 1/50 (0%)											
		` '				` '					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Pancreas: Mixed Tumor Benign											
		1/50 (2%)				0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Parathyroid Gland: Adenoma		0/45 (00/)				0/45 (00/)					
Overall Incidence	Total	0/45 (0%) 0/45 (0%)	Mean 0%	SD 0%	Total	0/45 (0%) 0/45 (0%)	Mean 0%	SD 0%			
		, ,				, ,					
*Pituitary Gland: Pars Distali Adenoma	is or Unspec	rified Site:									
		34/49 (69%)				36/50 (72%)					
Overall Incidence	Total	34/49 (69.39%)	Mean 69.39%	SD 0%	Total	36/50 (72%)	Mean 72%	SD 0%			
*Pituitary Gland: Pars Distali Carcinoma											
		0/49 (0%)				2/50 (4%)					
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%			
*Pituitary Gland: Pars Distali Carcinoma or Adenoma		ified Site:									
		34/49 (69%)				38/50 (76%)					
Overall Incidence	Total	34/49 (69.39%)	Mean 69.39%	SD 0%	Total	38/50 (76%)	Mean 76%	SD 0%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 228

			Ма	le			Female					
*Pituitary Gland: Pars Distalis or Unspecified Site: Ganglioneuroma												
ū		0/49 (0	%)			0/50 (0%)						
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Pituitary Gland: Pars Inter Adenoma	media:	0/49 (0'	%)			1/50 (2%)						
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%				
*Pituitary Gland: Pars Inter Carcinoma or Adenoma	rmedia:	0/49 (0'	0 <u>/</u> \			1/50 (2%)						
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%				
*Pituitary Gland: Pars Nerv Craniopharyngioma	osa:	0/49 (0'	0 <u>/</u> \			1/50 (2%)						
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%				
*Prostate: Adenoma		0/50 (0'	0/ \									
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%								
*Prostate: Carcinoma or Adenoma												
		,	%)									
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%								

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 229

			Male				Female	
*Salivary Glands: Carcinoma								
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma		•••••		•••••	•••••			
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: Schwannoma Malignant						0/50 /00()		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma		•••••		•••••	•••••			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Fibrous Histiocytoma						0/50 /00()		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 230

			Male				Female	
#Skeletal Muscle: Lipoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma								
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Basal Cell Adenoma or	·	0/50 (0%)	M 00/	OD 004	Total	1/50 (2%)	M 00/	0D 0W
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Basal Cell Adenoma, Ba	ısosquamous Tı	umor Benign, or Trich 0/50 (0%)	oepithelioma			1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Basal Cell Carcinoma		•••••						
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma o	r Basosquamou	s Tumor (malignant o	r NOS)			0/50 (0%)		
		0/30 (0%)				0/30 (0%)		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 231

Report Date: 06/05/2013

Length of Study: CHRONIC

			Male				Female						
	Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma												
		0/50 (0%)				1/50 (2%)							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%					
		a, Basosq. Tumor (M or E ratoacanthoma, Trichoep 5/50 (10%)		ma,		1/50 (2%)							
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%					
#Skin: Fibroma Overall Incidence	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%					
#Skin:		oma, Myxosarcoma, or Fi 4/50 (8%) 4/50 (8%)			Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%					
#Skin: Fibrosarcoma	Total	0/50 (0%)	Meall 070	35 0%	Total	0/50 (0%)	iviedii 076	30 0%					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%					
#Skin: Fibrosarcoma, Sarcom	a, Myxosarcoma	, or Fibrous Histiocytoma 0/50 (0%)	a			0/50 (0%)							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%					

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 232

Report Date: 06/05/2013

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

			Male				Female			
#Skin: Fibrous Histiocytoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Hemangiosarcoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Keratoacanthoma		4/50 (8%)				0/50 (0%)				
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Lipoma		2/50 (4%)				0/50 (0%)				
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Liposarcoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Skin: Neural Crest Tumor		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 233

Report Date: 06/05/2013

Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female			
#Skin: Neurofibroma or Schwa	nnoma benign								
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Skin:									
Neurofibrosarcoma or S	Schwannoma (m	•							
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin:									
Neurofibrosarcoma, Ne	urofibroma, or S	Schwannoma (benign,	malignant or NOS)						
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
Skin:							•••••		
Sarcoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
:Skin:							•••••		
Schwannoma Benign									
· ·		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
Skin:									
Schwannoma Malignan	t								
•		0/50 (0%)				0/50 (0%)			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 234

			Male				Female	
#Skin: Squamous Cell Carcino	oma							
-		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcino or Carcinoma	oma, Basal Cell (Carcinoma, Basosquamo	us Tumor (malignan	it or NOS),				
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillo	ma	1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillo	ma or Papilloma					0/50 (0)()		
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillo	ma, Papilloma, S	Squamous Cell Carcinoma 5/50 (10%)	a or Keratoacanthon	na		0/50 (0%)		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillo	ma, Papilloma, o	or Keratoacanthoma 5/50 (10%)				0/50 (0%)		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 235

			Male				Female	
#Skin: Trichoepithelioma	Total	0/50 (0%)	M 00/	OD 00/	Total	0/50 (0%)	M 00/	OD 004
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Spinal Cord: Glioma Malignant		0/50 (0%)		OD 00/	T. (-)	0/50 (0%)	M 00/	00.00
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma		0/50 (00/)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Groups Report Date: 06/05/2013

Page: 236

		Male				Female	
	0/50 (0%)				0/50 (0%)		
Total	` '	Mean 0%	SD 0%	Total		Mean 0%	SD 0%
Total	27/50 (54%)	Mean 54%	SD 0%				
Total	0/50 (0%)	Mean 0%	SD 0%				
Total	0/45 (0%)	Mean 0%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%
••••							
	0/45 (0%)				0/47 (0%)		
	()				, ,		SD 0%
	0/45 (0%)				0/47 (0%)		
Total	, ,	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
	Total Total Total	Total 0/50 (0%) 27/50 (54%) Total 27/50 (54%) 0/50 (0%) Total 0/50 (0%) Total 0/45 (0%) Total 0/45 (0%) Total 0/45 (0%) 0/45 (0%) 0/45 (0%)	0/50 (0%) Total 0/50 (0%) Mean 0% 27/50 (54%) Total 27/50 (54%) Mean 54% 0/50 (0%) Total 0/50 (0%) Mean 0% 0/45 (0%) Total 0/45 (0%) Total 0/45 (0%) Mean 0% 0/45 (0%) Mean 0%	0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% 27/50 (54%) Total 27/50 (54%) Mean 54% SD 0% O/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/45 (0%) Mean 0% SD 0% Total 0/45 (0%) Mean 0% SD 0% O/45 (0%) Total 0/45 (0%) Mean 0% SD 0%	Total 0/50 (0%) Mean 0% SD 0% Total 27/50 (54%) Total 27/50 (54%) Mean 54% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/45 (0%) Total 0/45 (0%) Mean 0% SD 0% Total 0/45 (0%) Mean 0% SD 0% Total 0/45 (0%) Total 0/45 (0%) Mean 0% SD 0% Total 0/45 (0%)	Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 27/50 (54%) Total 27/50 (54%) Mean 54% SD 0% Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/47 (0%) Total 0/45 (0%) Mean 0% SD 0% Total 0/45 (0%) Total 0/45 (0%) Mean 0% SD 0% Total 0/47 (0%) Total 0/45 (0%) Mean 0% SD 0% Total 0/47 (0%) Total 0/45 (0%) Mean 0% SD 0% Total 0/47 (0%)	Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% 27/50 (54%) Total 27/50 (54%) Mean 54% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/45 (0%) Mean 0% SD 0% Total 0/47 (0%) Mean 0% O/47 (0%) Mean 0% O/47 (0%) Mean 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 237

			Male				Female	
*Thymus: Thymoma: Benign, Maligi	nant, NOS	0/45 (0%)				0/47 (0%)		
Overall Incidence	Total	0/45 (0%)	Mean 0%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Adenoma								
Overall Incidence	Total	8/50 (16%) 8/50 (16%)	Mean 16%	SD 0%	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma						0/50 (00/)		
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		8/50 (16%)				3/50 (6%)		
Overall Incidence	Total	8/50 (16%)	Mean 16%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%
*Thyroid Gland: Follicular C Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular C Carcinoma						0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 238

				Male				Female	
*Thyroid Gland: Follicular C Carcinoma or Adenoma	Cell:								
		,	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Me	an 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinom	ıa								
		,	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Me	an 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinom		1/50 ((2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Me	an 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
							()		
#Tongue: Squamous Cell Papilloma			(2%)				0/50 (0%)		
#Tongue:		1/50 (1/50 (2%)	(2%) Me	an 2%	SD 0%	Total		Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma	a Total	1/50 (1/50 (2%)	(2%) Me	an 2%			0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma Overall Incidence #Tooth: Adamantinoma Malignant	Total	1/50 (1/50 (2%) 0/50 ((2%) Me 		SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%)		
#Tongue: Squamous Cell Papilloma Overall Incidence #Tooth:	a Total	1/50 (1/50 (2%)	(2%) Me 	an 2% an 0%			0/50 (0%) 0/50 (0%)	Mean 0% Mean 0%	SD 0% SD 0%
#Tongue: Squamous Cell Papilloma Overall Incidence #Tooth: Adamantinoma Malignant	Total	1/50 (1/50 (2%) 0/50 (0/50 (0%)	(2%) Me 		SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%)		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 239

				Male				Female			
*Urinary Bladder: Carcinoma or Papilloma											
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Urinary Bladder: Hemangiosarcoma											
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Urinary Bladder: Papilloma											
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Uterus: Adenoma							0/50 (0%)				
Overall Incidence						Total	0/50 (0%)	Mean 0%	SD 0%		
#Uterus: Carcinoma											
Overall Incidence						Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Uterus: Leiomyosarcoma							0/50 (00/)				
Overall Incidence						Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 240

Report Date: 06/05/2013

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ACETONE

	Male			Female		
#Uterus: Polyp Stromal						
Overall Incidence		Total	9/50 (18%) 9/50 (18%)	Mean 18%	SD 0%	
#Uterus: Sarcoma		•••••				
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Sarcoma Stromal		•••••				
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Sarcoma Stromal or Polyp Stromal						
Overall Incidence		Total	9/50 (18%) 9/50 (18%)	Mean 18%	SD 0%	
#Uterus: Schwannoma Malignant			0/50 (00/)			
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Vagina: Polyp						
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 241

		Male			Female			
				Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
				Total	0/50 (0%)	Mean 0%	SD 0%	
Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
	Total Total	1/50 (2%) Total 1/50 (2%) 0/50 (0%) Total 0/50 (0%)	1/50 (2%) Total 1/50 (2%) Mean 2% 0/50 (0%) Total 0/50 (0%) Mean 0%	1/50 (2%) Total 1/50 (2%) Mean 2% SD 0% 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0%	Total Total 1/50 (2%) Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total	Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Total 0/50 (0%)	Total 0/50 (0%) Total 0/50 (0%) Mean 0% Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Mean 0% Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Page: 242

Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Southern Research Institute	059500305	04/05/04	729	50(1)	27(683)	508.5	Methyl trans-styryl ketone
Battelle Columbus Laboratory	059903203	09/15/04	727	50(1)	23(651)	510.1	Pyrogallol
					Female		
Southern Research Institute	059500305	04/05/04	732	50(1)	30(685)	356.2	Methyl trans-styryl ketone
Battelle Columbus Laboratory	059903203	09/16/04	728	50(1)	29(670)	351.0	Pyrogallol

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 243 Report Date: 06/05/2013

			Male			Female			
#All Organs: Benign Tumors									
Overall Incidence	Total	46/50 (92%) 93/100 (93%)	47/50 (94%) Mean 93%	SD 1.41%	Total	47/50 (94%) 90/100 (90%)	43/50 (86%) Mean 90%	SD 5.66%	
#All Organs: Malignant Tumors									
Overall Incidence	Total	33/50 (66%) 55/100 (55%)	22/50 (44%) Mean 55%	SD 15.56%	Total	22/50 (44%) 34/100 (34%)	12/50 (24%) Mean 34%	SD 14.14%	
#All Organs: Malignant and Benign T	umors	40/50 (000)				40/50 (000/)	45/50 (000()		
Overall Incidence	Total	48/50 (96%) 97/100 (97%)	49/50 (98%) Mean 97%	SD 1.41%	Total	49/50 (98%) 94/100 (94%)	45/50 (90%) Mean 94%	SD 5.66%	
#All Organs: Hemangioma		0/50 (00/)				0/50 (00/)	0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#All Organs: Hemangiosarcoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#All Organs: Hemangiosarcoma or H	emangioma								
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 244

			Male			Female			
#All Organs: Histiocytic Sarcoma									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#All Organs: Leukemia: Lymphocytic,	, Monocytic, Ma	ononuclear, or Undifferen	itiated						
	•	26/50 (52%)	11/50 (22%)			18/50 (36%)	8/50 (16%)		
Overall Incidence	Total	37/100 (37%)	Mean 37%	SD 21.21%	Total	26/100 (26%)	Mean 26%	SD 14.14%	
Overall Incidence	Total	phocytic, Mixed, NOS, or 0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#All Organs: Mesothelioma: Benign, N		3							
Overall Incidence	Total	4/50 (8%) 6/100 (6%)	2/50 (4%) Mean 6%	SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#All Organs: Mesothelioma: Malignan	t								
Mesothelioma: Malignan		4/50 (8%)	2/50 (4%)			0/50 (0%)	0/50 (0%)		
	t Total	4/50 (8%) 6/100 (6%)	2/50 (4%) Mean 6%	SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
Mesothelioma: Malignan		` '	` '	SD 2.83%	Total	(,	` ,	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 245

Report Date: 06/05/2013

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#All Organs: Osteosarcoma								
		1/50 (2%)	0/50 (0%)	25		0/50 (0%)	0/50 (0%)	25
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma or Osteoma		1/50 (20()	0/50 /00/)			0/50 (00/)	4/50 (20/)	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
*Adrenal Cortex: Adenoma								
		0/50 (0%)	0/50 (0%)			4/50 (8%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	5/100 (5%)	Mean 5%	SD 4.24%
*Adrenal Cortex: Carcinoma		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Benign								
		11/49 (22%)	4/50 (8%)			1/49 (2%)	1/50 (2%)	
Overall Incidence	Total	15/99 (15.15%)	Mean 15.22%	SD 10.22%	Total	2/99 (2.02%)	Mean 2.02%	SD 0.03%
*Adrenal Medulla: Pheochromocytoma Comple	ex	0/40 (000)	0/50 (001)			0/40 /00:	0/50 (00/)	
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall illicidence	ıvıaı	0/99 (070)	IVICALI U70	עט עכ 0%	ı ∪ıal 	0/99 (070)	IVICALI U70	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 246

Report Date: 06/05/2013

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female						
*Adrenal Medulla: Pheochromocytoma Malignant													
		0/49 (0%)	1/50 (2%)			0/49 (0%)	0/50 (0%)						
Overall Incidence	Total	1/99 (1.01%)	Mean 1%	SD 1.41%	Total	0/99 (0%)	Mean 0%	SD 0%					
*Adrenal Medulla: Pheochromocytoma: B	Benign, Complex	•											
O	T-1-1	11/49 (22%)	5/50 (10%)	00.000	T-1-1	1/49 (2%)	1/50 (2%)	00.000/					
Overall Incidence	Total	16/99 (16.16%)	Mean 16.22%	SD 8.8%	Total	2/99 (2.02%)	Mean 2.02%	SD 0.03%					
#Blood Vessel: Leiomyosarcoma													
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)						
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%					
#Bone: Chordoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)						
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%					
#Bone: Osteoma													
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)						
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%					
#Bone: Osteosarcoma													
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)						
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%					

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 247

			Male				Female					
#Bone: Osteosarcoma or Osteoma												
		1/50 (2%)	0/50 (0%)			0/50 (0%)	1/50 (2%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
*Brain: Glioma												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Brain: Glioma Benign		0/50 (001)	0/50 (00/)			0(50 (00))	0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
		, ,			10tai	0/100 (0%)						
*Brain: Glioma Malignant		0/50 (00()	0/50 (00/)			0/50 (00/)	0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Brain: Oligodendroglioma, Glioma												
	•	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Brain: Osteosarcoma		0/50 (00/)	0/50 (00)			0/50 (001)	0/50 /00/					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
	Total	0/100 (0%)			Total	` '						

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 248 Report Date: 06/05/2013

			Male		Female			
*Clitoral/Preputial Gland: Adenoma								
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	6/50 (12%) 9/100 (9%)	3/50 (6%) Mean 9%	SD 4.24%
Clitoral/Preputial Gland: Carcinoma								
Overall Incidence	Total	3/50 (6%) 3/100 (3%)	0/50 (0%) Mean 3%	SD 4.24%	Total	3/50 (6%) 4/100 (4%)	1/50 (2%) Mean 4%	SD 2.83%
Clitoral/Preputial Gland: Carcinoma or Adenoma		4/50 (00/)	0/50 (00)			0/50 (400/)	4/50 (00)	
Overall Incidence	Total	4/50 (8%) 4/100 (4%)	0/50 (0%) Mean 4%	SD 5.66%	Total	9/50 (18%) 13/100 (13%)	4/50 (8%) Mean 13%	SD 7.07%
Clitoral/Preputial Gland: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Ear: Neural Crest Tumor								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
∉Eye: Melanoma Benign		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS **Strain:** F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 249

			Male				Female	
#Eye: Melanoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Harderian Gland: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%
#Harderian Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Harderian Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%
*Heart: Schwannoma Benign								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Heart: Schwannoma Malignant								
Overall Incidence	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Page: 250

			Male				Female					
#Intestine Large: Colon/Rectum: Adenoma												
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Intestine Large: Colon/Rect Carcinoma or Adenoma												
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Intestine Small: Duodenum: Leiomyoma	:											
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Intestine Small: Duodenum: Schwannoma Malignant												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Intestine Small: Ileum: Adenoma		•••••										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%				
#Intestine Small: Jejunum: Carcinoma												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Page: 251

			Male				Female						
#Intestine Small: Jejunum: Leiomyoma													
	.	0/50 (0%)	0/50 (0%)	05.00/	-	0/50 (0%)	0/50 (0%)	OD 00/					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%					
#Intestine Small: Jejunum: Leiomyosarcoma													
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)						
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%					
#Intestine Small: Site Unspec Adenoma	cified:												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)						
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%					
#Intestine Small: Site Unspec Carcinoma	cified:	0/50 (0%)	0/50 (00/)			0(50 (00))	0/50 (00/)						
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%					
#Intestine Small: Site Unspec Carcinoma or Adenoma	cified:												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)						
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%					
#Intestine Small: Site Unspec													
•		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)						
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%					

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 252

Report Date: 06/05/2013

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Intestine Small: Site Unsp Leiomyosarcoma	ecified:							
•		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp Schwannoma Malignant	ecified:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma								
		5/49 (10%)	3/50 (6%)			3/49 (6%)	2/50 (4%)	
Overall Incidence	Total	8/99 (8.08%)	Mean 8.1%	SD 2.97%	Total	5/99 (5.05%)	Mean 5.06%	SD 1.5%
*Islets, Pancreatic: Carcinoma		3/49 (6%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	3/99 (3.03%)	Mean 3.06%	SD 4.33%	Total	0/99 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma								
		8/49 (16%)	3/50 (6%)			3/49 (6%)	2/50 (4%)	
Overall Incidence	Total	11/99 (11.11%)	Mean 11.16%	SD 7.3%	Total	5/99 (5.05%)	Mean 5.06%	SD 1.5%
*Kidney: Pelvis and Transit Papilloma	tional Epitheli							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 253

			Male				Female	
*Kidney: Renal Tubule: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
'Kidney: Renal Tubule: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Lipoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
Kidney: Renal Tubule: Mesenchymal Tumor Malig	nant							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 254

			Male				Female					
*Liver: Hepatocellular Adenoma												
		2/50 (4%)	1/50 (2%)			0/50 (0%)	2/50 (4%)					
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 2.83%				
Liver: Hepatocellular Carcinoma												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Liver: Hepatocellular Carcinoma	or Hepatobla	u stoma 0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Liver: Hepatocellular Carcinoma			1/50 (2%)			0/50 (0%)	2/50 (4%)					
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 2.83%				
*Liver: Hepatocellular Carcinoma		lar Adenoma, or Hepatobl				0/50 (0%)	2/50 (4%)					
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 2.83%				
*Liver: Ito Cell Tumor Benign												
		0/50 (0%)	0/50 (0%)	00.00/		0/50 (0%)	0/50 (0%)	05.00/				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 255

			Male				Female					
*Lung: Alveolar/Bronchiolar Adenoma												
		2/50 (4%)	1/50 (2%)			1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
*Lung: Alveolar/Bronchiolar C	Carcinoma											
		0/50 (0%)	3/50 (6%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 4.24%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Lung: Alveolar/Bronchiolar C Overall Incidence	Carcinoma or Alve	eolar/Bronchiolar Adenom 2/50 (4%) 6/100 (6%)	na 4/50 (8%) Mean 6%	SD 2.83%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%				
*Lung: Fibrosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Mammary Gland: Adenolipoma												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Mammary Gland: Adenoma												
O	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	1/50 (2%)	2/50 (4%)	00 4 440/				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 1.41%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

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			Male				Female		
#Mammary Gland: Carcinoma				,					
		0/50 (0%)	1/50 (2%)			2/50 (4%)	1/50 (2%)		
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	3/100 (3%)	Mean 3%	SD 1.41%	
Mammary Gland: Carcinoma or Adenoma									
		0/50 (0%)	1/50 (2%)			3/50 (6%)	3/50 (6%)		
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	6/100 (6%)	Mean 6%	SD 0%	
#Mammary Gland: Fibroadenoma									
		2/50 (4%)	0/50 (0%)			19/50 (38%)	24/50 (48%)		
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	43/100 (43%)	Mean 43%	SD 7.07%	
Mammary Gland: Fibroma		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
Mammary Gland: Fibroma, Fibroadenoma or Ad	denoma								
		2/50 (4%)	0/50 (0%)			19/50 (38%)	25/50 (50%)		
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	44/100 (44%)	Mean 44%	SD 8.49%	
#Mammary Gland: Fibroma, Fibroadenoma, Card	cinoma, or	· Adenoma							
		2/50 (4%)	1/50 (2%)			21/50 (42%)	26/50 (52%)		
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	47/100 (47%)	Mean 47%	SD 7.07%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 257

Report Date: 06/05/2013

			Male				Female	
#Mesentery: Fibrous Histiocytoma								
Occupation of James	T-1-1	0/50 (0%)	1/50 (2%)	00 4 440/	Taral	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Mesentery: Schwannoma Malignan	t							
		1/50 (2%)	0/50 (0%)			0/50 (0%)	2/50 (4%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 2.83%
*Nose: Adenoma		0/50 (0%)	0/50 (0%)			0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Papilloma Squamous o Overall Incidence	a, Tongue, Phary	ynx, Tooth, Gingiva): 0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcino	a, Tongue, Phary	ynx, Tooth, Gingiva):						
		1/50 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos	a, Tongue, Phary		1/50 (2%)			0/50 (0%)	0/50 (0%)	
		1,00 (= 70)	1,00 (= /0)			0,00 (0,0)	3, 33 (3,3)	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 258

			Male				Female	
#Oral Mucosa: Squamous Cell Carcinoma								
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Oral Mucosa: Squamous Cell Papilloma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Cystadenoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Ovary: Fibrosarcoma						0/50 (00/)	0/50 (00/)	
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
'Ovary: Granulosa Cell Tumor Beni								
Overall Incidence					Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%
*Ovary: Granulosa Cell Tumor Maliç	ınant							
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS **Strain:** F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Page: 259

			Male				Female	
*Ovary: Granulosa Cell Tumor:	Benign, Maligna	nt, NOS				4/50 (00()	4/50 (00()	
Overall Incidence					Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%
*Ovary: Granulosa-Theca Tumo						0/50 (00/)		
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Schwannoma Malignan	t					0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%
*Ovary: Sertoli Cell Tumor Mali						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%
*Ovary: Tubulostromal Adenom	na							
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Adenoma								
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Page: 260

			Male				Female	
*Pancreas: Carcinoma or Adenoma								
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Mixed Tumor Benign								
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Parathyroid Gland: Adenoma								
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/99 (1.01%)	0/49 (0%) Mean 1%	SD 1.41%
*Pituitary Gland: Pars Dista								
Overall Incidence	Total	33/50 (66%) 66/100 (66%)	33/50 (66%) Mean 66%	SD 0%	Total	31/50 (62%) 56/100 (56%)	25/50 (50%) Mean 56%	SD 8.49%
*Pituitary Gland: Pars Dista Carcinoma								
Overall Incidence	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%
*Pituitary Gland: Pars Dista Carcinoma or Adenoma	-							
Overall Incidence	Total	35/50 (70%) 68/100 (68%)	33/50 (66%) Mean 68%	SD 2.83%	Total	33/50 (66%) 58/100 (58%)	25/50 (50%) Mean 58%	SD 11.31%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 261

Report Date: 06/05/2013

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female					
*Pituitary Gland: Pars Distalis or Unspecified Site: Ganglioneuroma												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Pituitary Gland: Pars Interi Adenoma	media:											
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Pituitary Gland: Pars Interi Carcinoma or Adenoma	media:											
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Pituitary Gland: Pars Nervo Craniopharyngioma	osa:											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Prostate: Adenoma												
		0/50 (0%)	0/50 (0%)									
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%								
*Prostate: Carcinoma or Adenoma												
		0/50 (0%)	0/50 (0%)									
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%								

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 262

Report Date: 06/05/2013

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Salivary Glands: Carcinoma		0/50 (00/)	4/50 (00)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma		0/50 (00/)	4/50 (00)			0/50 /00/	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Salivary Glands: Sarcoma		(00)	(00)			0.50	(00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Salivary Glands: Schwannoma Malignant		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma		0/50 (00/)	0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Skeletal Muscle: Fibrous Histiocytoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 263

Report Date: 06/05/2013

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female	
#Skeletal Muscle: Lipoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma or Overall Incidence	Basosquamous Total	Tumor Benign 0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
	Total	0/100 (0%)		5D 0%	ı otal	0/100 (0%)		3D 0%
#Skin: Basal Cell Adenoma. Ba	asosquamous T	umor Benign, or Trichoep	ithelioma					
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin:								
Basal Cell Carcinoma o	r Basosquamou	is Tumor (malignant or NC				0/50 (00/)	4/50 (20/)	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
Overall incluence	IUlai	1/100 (176)	IVICALI 170	SD 1.4170	TUlai	1/100 (170)	IVIEALI 170	3D 1.41%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 264

Report Date: 06/05/2013

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female	
#Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli		oma, Basosquamous Tun	nor (benign, maligna	nt or				
		1/50 (2%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
		a, Basosq. Tumor (M or E ratoacanthoma, Trichoep 7/50 (14%)	ithelioma	na,		0/50 (0%)	1/50 /(20/)	
Overall Incidence	Total	10/100 (10%)	3/50 (6%) Mean 10%	SD 5.66%	Total	1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Skin: Fibroma Overall Incidence	Total	5/50 (10%) 6/100 (6%)	1/50 (2%) Mean 6%	SD 5.66%	Total	3/50 (6%) 4/100 (4%)	1/50 (2%) Mean 4%	SD 2.83%
	-	oma, Myxosarcoma, or Fi 7/50 (14%)	1/50 (2%)			3/50 (6%)	1/50 (2%)	
Overall Incidence	Total	8/100 (8%)	Mean 8%	SD 8.49%	Total	4/100 (4%)	Mean 4%	SD 2.83%
#Skin: Fibrosarcoma		2/50 (4%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Fibrosarcoma, Sarcom		n, or Fibrous Histiocytoma 2/50 (4%)				0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

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			Male				Female	
#Skin: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Keratoacanthoma								
Overall Incidence	Total	4/50 (8%) 6/100 (6%)	2/50 (4%) Mean 6%	SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Lipoma		0/50 (00/)	0/50 (00/)			0/50 (0%)	0/50 (09/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Liposarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Neural Crest Tumor								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

			Male				Female	
#Skin: Neurofibroma or Schwan	noma benign	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma or Sc	hwannoma (m	- ,	- /					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Skin: Neurofibrosarcoma, Neur	ofibroma, or S	Schwannoma (benign, ma 0/50 (0%)	lignant or NOS) 0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Sarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Schwannoma Benign								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Schwannoma Malignant		0/50 (00/)	0/50 /00/			0/50 (09/)	1/50 (20/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male			Female						
#Skin: Squamous Cell Carcinoma 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%)												
Overall Incidence	Total	1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Skin: Squamous Cell Carcinoma or Carcinoma	, Basal Cell (Carcinoma, Basosquamoı	us Tumor (malignant	or NOS),								
Overall Incidence	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%				
#Skin: Squamous Cell Papilloma		4/50 (20/)	4/50 (20/)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Skin: Squamous Cell Papilloma	or Papilloma		4/50 (20/)			0/50 (0%)	0/50 (00/)					
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Skin: Squamous Cell Papilloma,						0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	9/100 (9%)	Mean 9%	SD 4.24%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skin: Squamous Cell Papilloma,			3/50 (6%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	8/100 (8%)	Mean 8%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Skin: Trichoepithelioma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma		0/50 (00/)	0/50 (00)			0(50 (004)	2/52 (224)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Spinal Cord: Glioma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma								
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

Species: RATS Strain: F 344/N Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

			Male				Female	
#Stomach, Glandular: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Testes: Adenoma		34/50 (68%)	37/50 (74%)					
Overall Incidence	Total	71/100 (71%)	Mean 71%	SD 4.24%				
*Testes: Hemangioma								
		0/50 (0%)	1/50 (2%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%				
*Thymus: Thymoma Benign		0/50 (0%)	0/47 (0%)			1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%
*Thymus: Thymoma Malignant								
		0/50 (0%)	0/47 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma NOS								
Overall Incidence	Total	0/50 (0%) 0/97 (0%)	0/47 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
		0/97 (0%)				` ,		SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 270

			Male				Female	
*Thymus: Thymoma: Benign, Maligna	ant, NOS							
		0/50 (0%)	0/47 (0%)			1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%
*Thyroid Gland: C-Cell: Adenoma								
		6/46 (13%)	9/50 (18%)			7/50 (14%)	7/50 (14%)	
Overall Incidence	Total	15/96 (15.62%)	Mean 15.52%	SD 3.5%	Total	14/100 (14%)	Mean 14%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma								
		0/46 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/96 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma								
Overall Incidence	Total	6/46 (13%) 15/96 (15.62%)	9/50 (18%) Mean 15.52%	SD 3.5%	Total	8/50 (16%) 15/100 (15%)	7/50 (14%) Mean 15%	SD 1.41%
	10tai	15/96 (15.62%)	10.52%	ას ა.ა%	ı Olal	15/100 (15%)	10%	3D 1.41%
*Thyroid Gland: Follicular Ce Adenoma	ell:							
		0/46 (0%)	0/50 (0%)			1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	0/96 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%
*Thyroid Gland: Follicular Ce Carcinoma	ell:							
		2/46 (4%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/96 (2.08%)	Mean 2.17%	SD 3.07%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

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			Male				Female	
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma	l:							
		2/46 (4%)	0/50 (0%)			1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	2/96 (2.08%)	Mean 2.17%	SD 3.07%	Total	2/100 (2%)	Mean 2%	SD 0%
#Tongue: Squamous Cell Carcinoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma o	or Papillom	a Squamous 0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tooth: Adamantinoma Malignant		2(72)	2/52 (221)			2(72)	2/22 (22)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

Report Date: 06/05/2013

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			Male				Female	
Urinary Bladder: Carcinoma or Papilloma		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/30 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangiosarcoma		0/50 (00/)	0/50 (00)			0/50 (00)	0/50 (00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Urinary Bladder: Papilloma		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
Uterus: Adenoma						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%
Uterus: Carcinoma						2/22 (221)	(00)	
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Uterus: Leiomyosarcoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

Toxicology Data Management System

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Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Male **Female #Uterus: Polyp Stromal** 10/50 (20%)7/50 (14%) **Overall Incidence** Total 17/100 (17%) Mean 17% SD 4.24% **#Uterus:** Sarcoma 0/50 (0%)1/50 (2%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% #Uterus: Sarcoma Stromal 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% #Uterus: Sarcoma Stromal or Polyp Stromal 10/50 (20%)7/50 (14%) **Overall Incidence** Total 17/100 (17%) Mean 17% SD 4.24% #Uterus: Schwannoma Malignant 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% #Vagina: Polyp 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 274

			Male				Female	
#Vagina: Sarcoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Vagina: Schwannoma Malignant								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Zymbal's Gland: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma			4/50 (00/)			0/50 (0%)	0/50 (00/)	
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied